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Supreme Court of the United States

McNeil–P.P.C., Inc.,

Petitioner,

—v.—

Armando Valdes, III, incapacitated, by and through his legal guardians, Armando Valdes, Jr. and Violetta Valdes, and Armando Valdes, Jr. and Violetta Valdes, individually,

Respondents.

ON PETITION FOR WRIT OF CERTIORARI TO THE DISTRICT COURT OF APPEAL OF FLORIDA, THIRD DISTRICT

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Over-the-counter ("OTC") drug products that comply with all mandatory conditions described in a "Final Monograph" are recognized as "safe and effective and not misbranded." 21 C.F.R § 330.1. The specific warnings for all OTC Final Monograph drugs are authored by the Food and Drug Administration ("FDA"), and codified into law. *Id.* Warnings "shall be in the exact language" established in an applicable OTC Final Monograph. 21 C.F.R. § 330.1(c)(2). The Federal Food, Drug, and Cosmetic Act ("FDCA") section entitled "National Uniformity for Nonprescription Drugs" provides that no state may establish any requirement that is "different from or in addition to, or that is otherwise not identical with," a requirement of the FDCA. 21 U.S.C. § 379r.

The question presented is whether federal law, which imposes a strict set of labeling requirements on manufacturers of Final Monograph OTC drugs, including mandatory product warnings authored by the FDA, pre-empts state-law product liability actions premised on theories of failure to warn.

LIST OF ALL PARTIES

Appellants in the Court Below

Armando Valdes. III, Incapacitated, by and through his legal guardians, Armando Valdes, Jr, and Violetta Valdes;

Armando Valdes, Individually

Violetta Valdes, Individually

Appellee in the Court Below

McNeil P.P.C. Inc.

CORPORATE DISCLOSURE STATEMENT

McNeil–P.P.C., Inc. is a wholly owned subsidiary of Johnson & Johnson.

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OPINIONS BELOW

The decision of the Third District Court of Appeal of Florida is reported at 27 So. 3d 689 (Fla. 3d DCA 2009) and reprinted in the Appendix ("App.") at 1a-5a. The trial court's decision granting Petitioner's Motion for Final Summary Judgment is reprinted at App. 10a-13a.

JURISDICTION

The Third District Court of Appeal issued *Valdes v. Optimist Club of Suniland, Inc.*, 27 So. 3d 689 (Fla. 3d DCA 2009), on December 30, 2009, App. 1a-5a, and denied a motion for rehearing on February 23, 2010, App. 6a. The Supreme Court of Florida denied McNeil-P.P.C's Petition for Discretionary Review on August 2, 2010, App. 8a. On October 22, 2010, Justice Thomas granted an extension until December 1, 2010 for the filing of this Petition.

This Court has jurisdiction pursuant to 28 U.S.C. § 1257(a).

PERTINENT CONSTITUTIONAL, STATUTORY, AND REGULATORY PROVISIONS

The pertinent constitutional, statutory and regulatory provisions are set forth in the Appendix, 52a-100a.

INTRODUCTION

In *Valdes v. Optimist Club of Suniland*, 27 So. 3d 689 (Fla. 3d DCA 2009), Florida's Third

District Court of Appeal held that state law failure to warn claims against the manufacturer of an over-the-counter ("OTC") drug product were not pre-empted by federal law set forth in a federal regulation known as a Final Monograph, which requires the manufacturer to use the warnings authored by the Food and Drug Administration ("FDA"). The Florida appellate court determined that it was constrained by *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), in which this Court rejected Wyeth's broad claim that state-law failure-to-warn claims against it were categorically pre-empted by FDA approval of the warnings for its prescription product, Phenergan. Among other things, this Court rejected a claim of implied conflict pre-emption based on Wyeth's assertion that it was impossible to strengthen its product warnings without prior approval of the FDA.

In rejecting Wyeth's implied conflict pre-emption argument, this Court relied on specific statutes and regulations applicable to manufacturers of brand-name prescription drugs, which allow the manufacturer to strengthen product warnings without prior FDA approval, pursuant to a "changes being effected" ("CBE") procedure. The appellate court in *Valdes* ignored the fact that prescription and OTC drugs are subject to different federal regulatory regimes. The appellate court failed to recognize that federal laws applicable to manufacturers of OTC products do not provide a mechanism similar to the CBE procedure that would permit a manufacturer to unilaterally change the warnings on product labeling crafted by the FDA. Because the *Valdes* court did not appreciate this crucial distinction, the court erred in concluding that state-law failure-to-warn

claims were not pre-empted by specific federal regulations that apply to OTC product manufacturers.

The Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (the "FDCA"), and its implementing regulations, provide distinct regulatory regimes for different drug products such as brand-name prescription drugs, generic prescription drugs, and over-the-counter (or nonprescription) drugs. Each regulatory scheme presents a unique set of laws, unique Congressional purposes, and a unique set of mechanisms that affect the safety, cost and efficacy of drugs in our public health system.

For purposes of the FDCA, a prescription drug includes any drug that "because of its toxicity or other potentiality for harmful effect . . . is not safe for use except under the supervision of a practitioner licensed by law to administer such a drug." 21 U.S.C. § 353 (b)(1)(A). Prescription drugs fall into two broad categories for regulatory purposes: brand-name and generic. A manufacturer seeking to market a new brand-name prescription drug must submit a new drug application ("NDA") to the FDA for approval. The NDA must include scientific information, a list of the drug's components, and samples of the proposed labeling for the drug. 21 U.S.C. § 355 (b)(1). The FDA will approve the NDA if it determines the drug is "safe for use." 21 U.S.C. § 355 (d)(1) and (5).

After approval of an NDA, any manufacturer may request approval for a generic version by submitting an abbreviated new drug application ("ANDA"). 21 U.S.C. § 355(j). Rather than submitting independent evidence of safety and effi-

cacy, the manufacturer must show that the generic drug has the same listed ingredients as the "reference listed drug" (the brand-name drug) and that the "labeling proposed for the [generic] drug is the same as the labeling approved for" the brand-name drug. 21 U.S.C. § 355(j)(2)(A) (ii), (iv) and (v).

OTC drugs are drugs that do not meet the statutory definition of "prescription" drugs and, thus, do not require a physician's supervision for their use by a consumer. OTC drugs that have not previously been approved by the FDA pursuant to the NDA or ANDA process can be marketed without prior approval of the FDA if they comply with regulations applicable to categories of products and set forth in an FDA Final Monograph. 21 C.F.R. § 330.1. Broad categories of OTC products for which Final Monographs exist include antacids, contraceptives, and cold and cough remedies.

Under the Final Monograph system, no manufacturer may sell an OTC drug unless its label strictly complies with categorical, mandatory labeling language, which is written by the FDA after formal notice-and-comment rulemaking and codified into law as a Final Monograph. *See* 21 U.S.C. § 332 (injunction proceedings), 333 (penalties), 334 (seizure); 21 C.F.R. § 330.10(b) (subjecting "[a]ny product which fails to conform to an applicable monograph" to regulatory action). This process differs significantly from the NDA system, under which the manufacturer—not the FDA—is responsible for the contents of the label on its prescription drug. Further, under the NDA process, the manufacturer—not the FDA—must ensure that its warnings remain adequate throughout the

marketing life of the drug, and the manufacturer has the ability—through "changes being effected" (CBE) regulations, which do not exist for OTC products—to change its drug label to "add or strengthen" warnings or instructions to increase the safe use of its drug without first obtaining FDA approval. 21 C.F.R. § 314.70(c)(6)(iii)(A), (C).

This Court's decision in *Wyeth* has been applied in some cases by lower courts to regulatory regimes outside the context of brand-name prescription drugs. Within a matter of months after the Florida court's decision in *Valdes*, the Seventh Circuit Court of Appeals cited *Wyeth* for the proposition that courts are free to hold "that state law requires warnings on the label of an over-the-counter drug beyond what the FDA has required." *Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 869 (7th Cir. 2010). These courts have misapplied *Wyeth* by giving it an overly broad application. These decisions would allow state court juries to override the federal Final Monograph regulatory regime put into place by the FDA for OTC products, which has no relationship to the NDA process governing prescription drugs.

The confusion created by the overly-broad application of *Wyeth* outside the context of brand-name prescription drugs has placed the entire OTC drug industry at risk in the United States. This issue affects more than "300,000 marketed OTC drug products . . . and the labeling of over 80 therapeutic classes of drugs"[1] classified into 26 Final

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[1] *See* FDA, *Drug Applications for Over-the-Counter Drugs* (last updated April 26, 2010) http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/Over-the-CounterDrugs/default.htm, App. 137a-140a.

Monograph categories[2] and marketed by at least 26 manufacturers[3] in an annual market that exceeds $16 billion.[4] The OTC drugs at issue in this case, Tylenol Cold and Tylenol Flu, are only two of over 700 products on the market governed by a single FDA OTC Final Monograph for nasal decongestants containing the active ingredients pseudoephedrine and ephedrine.[5]

Granting this petition would enable the Court to resolve the overbroad and conflicting misapplication of *Wyeth* to a regulatory regime in which the intent of Congress and the goal of the FDA was to develop across-the-board drug labeling containing a specific set of cautions and instructions applying to *categories* of drugs in a process designed to permit relatively easy access to the OTC market and ensure low-cost, prescription-free consumer access to safe, time-tested, and properly-labeled medicines. This is in contrast to the NDA process, which applies only to *individual* prescription drugs, each of whose warnings are developed by the manufacturer and approved by the FDA.

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[2] *See* 21 C.F.R. § 330.5.

[3] *See* Drug InfoNet, Pharmaceutical Manufacturer Information, Over the Counter/Consumer Drug Manufacturers (visited Oct. 22, 2010) <http://www.druginfonet.com/manufacturers.htm>, App. 132a-136a.

[4] *See* Consumer Healthcare Products Association, *OTC Facts & Figures* (The Nielsen Company, 2009) <http://www.chpa-info.org/pressroom/OTC_FactsFigures.aspx>, App. 130a-131a.

[5] *See* State of Indiana, Criminal Justice Institute, Pseudoephedrine and Ephedrine Product List (visited Oct. 21, 2010) http://www.in.gov/cji/files/Product_List.pdf, App. 141a-169a.

Both Congress and the FDA have recognized that uniformity is essential to ensure safety in the OTC drug market. Congress's stated purpose in amending the Federal Food, Drug, and Cosmetic Act in 1997 was to ensure "national uniformity" in the laws governing nonprescription drug products. 21 U.S.C. § 379r. But the Florida court in *Valdes* and the Seventh Circuit in *Robinson* did not address Congressional purpose regarding OTC drugs. Recognition of the distinct Congressional purposes with regard to OTC drugs is essential in considering whether pre-emption applies. *Medtronic v. Lohr*, 518 U.S. 470, 485 (1966). Overbroad misapplication of *Wyeth* to the OTC Final Monograph regulatory regime defeats the fundamental Congressional purpose of national uniformity, renders compliance by OTC manufacturers with federal regulations impossible, and threatens to eviscerate the concept of federal pre-emption in all drug cases, regardless of statutory regime or Congressional intent.

In *Wyeth*, this Court commented that "we have no occasion in this case to consider the pre-emptive effect of a specific agency regulation bearing the force of law." 129 S. Ct. at 1203. In a concurring opinion, Justice Breyer emphasized that comment. Justice Breyer noted it is "possible that state tort law will sometimes interfere with the FDA's desire to create a drug label containing a specific set of cautions and instructions" and "it is possible that such determinations would have pre-emptive effect." 129 S. Ct. at 1204 (Breyer, J., concurring). The OTC Final Monograph at issue here is "a specific agency regulation bearing the force of law," and it contains "a specific set of cautions and instructions" authored by the FDA. *See*

21 C.F.R. § 341.80 ("Labeling of nasal decongestant products").

Granting McNeil's Petition would give this Court the opportunity to rule on a significant pre-emption issue specifically left open by *Wyeth*. The Court would be able to clarify the pre-emptive effect of FDA regulations bearing the force of law that require OTC products to use a specific set of warnings in order to be considered "safe" and "not misbranded." 21 C.F.R. § 330.1. At the same time, this Court could clarify the confusion stemming from overbroad application of *Wyeth* by lower courts.

STATEMENT OF THE CASE

A. Factual Background

1. FDA Regulatory Regime for OTC Drugs.

The Federal Food, Drug and Cosmetic Act ("FDCA") together with implementing regulations of the Food and Drug Administration ("FDA"), provide a comprehensive scheme of drug regulation. Since its enactment in 1938, the FDCA has been amended on a number of occasions. Amendments enacted in 1962 added requirements that drugs must be not just safe, but effective as well, and that the labeling of a drug cannot be false or misleading. *See Mills v. Warner-Lambert Co.*, 581 F. Supp. 2d 772, 783 (E.D. Tex. 2008). The 1962 amendments required the FDA to examine all marketed drugs for their effectiveness, whether or not they had been approved previously.

The FDA recognized that it could not possibly evaluate each of the prescription and OTC drugs already on the market without assistance. *Id.; see Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 650 (1973) (recognizing that in 1973 there were between 100,000 and 500,000 OTC drugs on the market, most of which had not been previously approved by the FDA). Accordingly, the FDA enlisted the National Academy of Sciences—National Research Council to create panels of experts to evaluate categories of OTC drugs. *Mills*, 581 F. Supp. 2d at 783. The Academy established seventeen advisory panels of outside experts to review twenty-six categories of OTC drugs, which were grouped by their intended effect (*i.e.* antacids, cold remedies). This approach was deemed prudent because although there are hundreds of thousands of OTC products, the drugs contain a relatively small number of active ingredients. *Id.* at 784.

The purpose of the review of OTC products was to ensure that the products were safe and not misbranded. This is known as the "monograph process." *Id.*[6] The detailed four-step procedure for classifying OTC drugs as "generally recognized among qualified experts as safe and effective for use and not misbranded" is set forth in 21 C.F.R. § 330.10. In the first step, the FDA Commissioner appoints an advisory review panel of qualified, independent experts for each designated OTC drug category to evaluate the safety and effec-

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[6] As the *Mills* court noted, a "monograph" is defined by Webster's Third New International Dictionary (1986) as "a learned detailed thoroughly documented treatise covering exhaustively a small area of a field of learning." *Mills*, 581 F. Supp. 2d at 784, n.9.

tiveness of OTC drugs, to review OTC drug labeling, and to advise on the promulgation of monographs. 21 C.F.R. § 330.10(a)(1). The panel then reports its conclusions and recommendations to the FDA "with respect to the safety and effectiveness of the drugs" in the designated OTC category. *Id.*

In the second step, the FDA reviews the expert panel's findings and then publishes a notice in the Federal Register requesting interested persons to submit for review and evaluation by the advisory panel "published and unpublished data and information pertinent to a designated category of OTC drugs." *Id.* at (a)(2). The advisory panel meets "as often and for as long as is appropriate" to review the data submitted to it and to prepare a report "with respect to the safety and effectiveness of the drugs in a designated category of OTC drugs." *Id.* at (a)(3). The panel may consult any individual or group; interested persons may request permission to present oral views to the panel. *Id.*

After the FDA Commissioner reviews the expert panel's conclusions and recommendations, the Commissioner is required to publish in the Federal Register a proposed order containing, among other things, a monograph establishing conditions under which a category of OTC drugs is "generally recognized as safe and effective and not misbranded." 21 C.F.R. § 330.10(a)(6)(i). The publication must contain the full report of the panel, and interested persons are allowed to file comments and documents. *Id.* at (a)(6)(iv). After reviewing all comments and any new data and information, the Commissioner is required to publish in the Federal Register a tentative order con-

taining a monograph establishing conditions under which a category of OTC drugs is "generally recognized as safe and effective and not misbranded." 21 C.F.R. § 330.10(a)(7)(i). Again, interested persons are permitted to file written comments or objections. *Id.* The FDA then considers any comments regarding the monograph and conducts an oral hearing if there are "reasonable grounds" for doing so. 21 C.F.R. § 330.10(a)(8).

In the fourth and final phase, the FDA, "[a]fter reviewing [any] objections, the entire administrative record including all new data and information and comments, and considering the arguments at any oral hearing," publishes in the Federal Register "a final order containing a monograph establishing conditions under which a category of OTC drugs . . . is generally recognized as safe and effective and not misbranded." 21 C.F.R. § 330.10(a)(9).

The Final Monograph for a class of OTC drugs includes labeling requirements. The manufacturer of an OTC product must use the exact warning language authored by the FDA. The Code of Federal Regulations provides that "***labeling*** under this subchapter and subchapter C *et seq.* of this chapter ***shall be stated in the exact language where exact language has been established and identified by quotation marks in an applicable OTC drug monograph or by regulation***[.]" 21 C.F.R. § 330.1(c)(2) (emphasis added). The FDA's labeling requirements are designed to provide warnings reflecting known risks based on reliable scientific evidence. *See generally* 21 C.F.R. § 330.10(a) (procedure for establishing OTC

monograph); § 341.80 (labeling of nasal decongestant drug products). Adequate warnings are those that, in the judgment of the FDA, are "clear and truthful in all respects, not misleading in any particular," and that accurately communicate the benefit to risk ratio and the proper use of the product in terms "likely to be read and understood by the ordinary individual." 21 C.F.R. § 330.10(a)(4)(v).

Compliance with the Final Monograph by the OTC drug manufacturer is mandatory. "Any product which fails to conform to an applicable monograph after its effective date is liable to regulatory action." 21 C.F.R. § 330.10(b). Therefore, once a Final Monograph goes into effect, it is illegal to sell a drug described therein unless it conforms to the monograph. *See generally* 21 U.S.C. §§ 332-334. If a drug is marketed without prior FDA approval or without complying with an applicable monograph, the United States may bring an enforcement action under the FDCA. *Id.* Enforcement measures include seizure of the drug product, civil injunction against its sale and criminal penalties against the violator. *Id.*

Another significant amendment to the FDCA, as pertinent to OTC products, was the 1997 Food and Drug Modernization Act ("Modernization Act") which expressly states Congress's fundamental purpose of national uniformity in the regulation and labeling of nonprescription drugs. 21 U.S.C. § 379r. Section 379r, entitled "National Uniformity for Nonprescription Drugs," provides in relevant part:

> (a) In general
>
> Except as provided in subsection (b), (c)(1), (d), (e), or (f) of this section, ***no State or***

> ***political subdivision of a State may establish or continue in effect any requirement***
>
> * * *
>
> (2) ***that is different from or in addition to, or that is otherwise not identical with, a requirement under this chapter***. . . .

Id. (emphasis added).

As demonstrated by the legislative history of the Modernization Act, "[d]ifferent or additional requirements at the State or local level can work against our national marketplace, confuse consumers, raise prices, undermine public confidence in our regulatory system and in products important to public health, and result in divergent public health protection throughout the country." S. Rep. No. 105-43, at 64 (1997), App. 101a-127a. Accordingly, Congress specifically expressed its intent to achieve national uniformity in connection with OTC drug labeling:

> Section 808 of the legislation therefore established a new section 761 of the Federal Food, Drug, and Cosmetic Act that adopts, as a general rule, the requirement of national uniformity in the regulation of nonprescription drugs and cosmetics and their constituents. No State or local government is permitted to impose different or additional requirements that relate to the subject matter covered by the three Federal laws as they apply to nonprescription drugs and cosmetics. These include requirements imposed on product manufacture or composition, labeling, advertising, or any other form of public notification or communication.

Id.

The Modernization Act also reinforces the well-recognized role of the FDA with regard to non-prescription drugs:

> Nonprescription drugs are subject to careful and comprehensive regulation by the FDA. The conditions under which nonprescription drugs are considered safe and effective, for use by the lay consumer, are specified by the FDA in nonprescription drug monographs or by new drug and antibiotic drug applications. The FDA also ensures that the labeling of nonprescription drugs provides adequate directions for use, and adequate warnings against unsafe use, through these monographs and drug marketing applications, as well as through a number of general and specific labeling regulations.

Id.

2. FDA's Final Monograph Regulation of OTC Nasal Decongestants

The 1994 approval of the Final Monograph for OTC nasal decongestants (including those containing pseudoephedrine products) was the result of a *22-year-long process*. The process began in 1972, when the FDA Commissioner signed the final regulations providing for OTC drug review and published in the Federal Register a specific request for data and information on all cold, cough, allergy, bronchodilator and antiasthmatic (CCABA) active ingredients.[7] A notice of a pro-

[7] Procedures for Classification of Over-the-Counter Drugs, 37 Fed. Reg. 9464 (1972); Over-The-Counter Cold,

posed monograph was published in the Federal Register on September 9, 1976.[8] The proposed monograph was the result of the evaluation of data by the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products.[9]

After review and evaluation of comments submitted, the advisory panel issued a tentative Final Monograph for OTC nasal decongestant products on January 15, 1985, which was published in the Federal Register.[10] Interested persons were invited to file written comments, objections, or requests for oral hearing before the Commissioner of the FDA regarding the proposed monograph.

At all times during the process, the FDA and the expert advisory panel considered any data relevant to the tentative Final Monograph and published corrections or changes to the monograph based upon the safety and effectiveness of the products subject to the monograph. For example, in 1992, the FDA published a notice to amend the tentative Final Monograph for OTC nasal decon-

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Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products, 37 Fed. Reg. 16029 (1972) .

[8] Establishment of a Monograph for OTC Cold, Cough, Allergy, Bronchodilator and Antiasthmatic Products, 41 Fed. Reg. 38312 (1976).

[9] *See* Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Final Monograph for OTC Nasal Decongestant Drug Products ("Final Monograph"), 59 Fed. Reg. 43386 (1994).

[10] Cold, Cough, Allergy, Bronchodilator and Antiasthmatic Products for Over-the-Counter Human Use; Tentative Final Monograph for Over-the-Counter Nasal Decongestant Drug Products, 50 Fed. Reg. 2220 (1985).

gestant drug products to modify the drug interaction precaution statement to warn against taking such products if a consumer was also taking a prescription drug containing a monoamine oxidase inhibitor (MAOI) without first consulting a physician.[11]

On August 23, 1994, the FDA issued its Final Monograph establishing the conditions under which OTC nasal decongestant products are generally recognized as safe and effective and not misbranded. *See* Final Monograph, 59 Fed. Reg. 43386 (codified at 21 C.F.R. pt. 341). This Final Monograph included precise labeling requirements (including warnings) for OTC nasal decongestants containing pseudoephedrine (and other active ingredients). 21 C.F.R. § 341.80.

3. The Operative FDA Warning Label

The FDA-authored mandatory warnings for OTC nasal decongestants containing pseudoephedrine are set forth in 21 C.F.R. § 341.80(c), App. 54a-68a. The labels on McNeil's Tylenol Cold and Tylenol Flu use the language required by the regulation, App. 128a-129a.

Tylenol Cold and Tylenol Flu are both multi-symptom products containing permitted combinations of active ingredients in addition to pseudoephedrine. McNeil's product labeling sets forth warnings required for those other active

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[11] Cold, Cough, Allergy, Bronchodilator and Antiasthmatic Products for Over-the-Counter Human Use; Proposed Amendment of Tentative Final Monograph for Over-the-Counter Nasal Decongestant Drug Products, 57 Fed. Reg. 27658 (1992).

ingredients, such as acetaminophen (for pain and fever) and dextromethorphan hydrobromide (a cough suppressant and antitussive). *See, e.g.*, 21 C.F.R. § 341.74(c)(1) (the regulation containing the Final Monograph for antitussive drug products).[12] It is undisputed that McNeil's labeling fully complied with all applicable federal regulations.

B. Proceedings Below

1. The Trial Court Proceedings

While playing roller hockey, 16-year-old Armando Valdes allegedly suffered heatstroke and cardiorespiratory arrest. Respondents brought alternative state law liability claims against Defendants Optimist Club of Suniland, Optimist International, the Sports Authority, Inc., JOFA AB, KHF Sports OY, The Hockey Company, and McNeil–P.P.C.[13] Respondents based their claim

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[12] Pursuant to other FDA regulations and guidelines, one of these warnings, set forth in 21 C.F.R. § 341.80(c)(1)(i)(B) ("If symptoms do not improve within 7 days or are accompanied by fever, consult a doctor."), is slightly modified to take into account the required warning for acetaminophen. The warning for acetaminophen containing products must state "Do not take this product for pain for more than 10 days or for fever for more than 3 days unless directed by a doctor." 21 C.F.R. § 343.50(c)(1). As required by the FDA, these warnings were consolidated in the most restrictive manner and are set forth in the subject label as "Do not take for pain for more than 7 days or for fever for more than 3 days unless directed by a doctor."

[13] Respondents alleged that the Optimist Club defendants acted negligently when they allowed Armando to play hockey in extreme heat and without safe protocols; that the Sports Authority was negligent for selling improper equipment without sufficient ventilation for roller hockey; and that JOFA, KHF and The Hockey Company, the

against McNeil solely upon an alleged failure to warn. Respondents alleged that Armando Valdes took either Tylenol Cold or Tylenol Flu, and had at least one caffeinated beverage prior to playing roller hockey. According to the Respondents, Tylenol Cold and/or Tylenol Flu, which contains pseudoephedrine, "increased the risk of heat-related illness and heart-related risks when ingested with caffeinated products and coupled with strenuous or athletic events in a hot environment like that of South Florida." *Valdes*, 27 So. 3d at 690. Respondents alleged that McNeil's "failure to warn of these risks on the labels of the Tylenol Cold/Flu packaging breached Florida state law requirements." *Id.* McNeil asserted its affirmative defenses, including federal pre-emption.

The trial court granted McNeil's motion for final summary judgment on federal pre-emption grounds. Among other things, the trial court specifically found that implied conflict pre-emption applied because it would have been impossible for McNeil to comply with federal regulations that mandate the exact warnings for labels of all OTC pseudoephedrine-containing products (including those sold by McNeil) while also meeting state common law jury determinations of whether the FDA-crafted warnings were adequate. The trial court also concluded that permitting Florida to enforce a common law duty to warn would defeat the fundamental federal objective of national uniformity in the labeling of OTC Final Monograph drugs, App. 10a-13a. The trial court

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manufacturers of the helmet and gloves used by Armando, were negligent and strictly liable for having sold products that were defective, App. 17a-51a.

entered judgment in accordance with its ruling, App. 14a-16a.

2. The Appeal to the Third District Court of Appeal of Florida

Respondents appealed to the Third District Court of Appeal of Florida. After their initial brief was filed, this Court issued its decision in *Wyeth v. Levine*, which rejected a brand-name prescription drug manufacturer's argument that FDA approval of its product's warnings pre-empted state law failure to warn claims. This Court found that it was not impossible for Wyeth to strengthen its product warnings because Wyeth could take advantage of a "changes being effected" provision, applicable to prescription drugs approved under the NDA procedure, and change its labeling without first seeking FDA approval. This Court also concluded that imposing liability on Wyeth for the alleged inadequacy of its warning would not stand as an obstacle to the accomplishment of federal regulatory requirements and purposes. *Wyeth*, 129 S. Ct. at 1204.

Florida's appellate court reversed the final summary judgment for McNeil, finding that "the facts in *Wyeth* are similar to the ones here, and the arguments made by the prescription drug manufacturer are practically identical to those advanced by McNeil." *Valdes*, App. 4a. The Florida court addressed no case other than *Wyeth*, and the federal regulations applicable to McNeil's products were not cited in the opinion.

The appellate court did not address McNeil's argument that *Wyeth* involved an entirely distinguishable regulatory regime. Regulations

governing an NDA allow the manufacturer to change its warning without prior approval from the FDA. Conversely, the OTC Final Monograph regulations do not contain a "changes being effected" (CBE) provision. Rather, all manufacturers of OTC nasal decongestant products containing pseudoephedrine are required to use the identical labeling language set forth in the Final Monograph codified into law. *See* 21 C.F.R. § 330.10(b).

The appellate court did not address McNeil's claim that principles of implied pre-emption applied because it was impossible for McNeil to comply with the applicable Final Monograph as well as state law, which, according to the Respondents, would require additional warnings that did not conform to the monograph. In addition, the appellate court failed to address McNeil's argument that permitting Florida to enforce its traditional common law duty to warn would stand as an obstacle to the accomplishment of the fundamental Congressional objective of national uniformity in the labeling of nonprescription drugs.

The appellate court failed to recognize how its decision would impact the actions of the other OTC product manufacturers using the identical FDA warnings on their pseudoephedrine products. Nor did it address how the decision would affect the conduct of manufacturers of OTC Final Monograph products in other categories of drugs. All manufacturers of OTC Final Monograph drugs are required to use the identical FDA-crafted warnings as codified in the Final Monographs governing over 26 OTC drug categories. *See* 21 C.F.R. § 330.5.

The appellate court never contemplated whether its ruling would require every manufacturer to acquire an equivalent knowledge base which would need to be continually updated, or whether the cost of doing so would be reflected in the prices of the OTC drugs approved by the Final Monograph process. Such a requirement would surely diminish the ability of manufacturers of Final Monograph OTC drugs to continue to sell their products pursuant to the mandatory provisions of the monograph, as Congress intended.

3. The Appeal to the Supreme Court of Florida

On March 26, 2010, McNeil sought discretionary review by the Supreme Court of Florida because the Third District's decision had the effect of construing the Supremacy Clause of the United States Constitution. *See* Fla. R. App. P. 9.030(a)(2)(A)(ii) (providing for discretionary jurisdiction to review decisions of district courts of appeal that construe a provision of the state or federal constitution). On August 2, 1010, the Supreme Court of Florida denied McNeil's Petition for Discretionary Review, App. 8a.

REASONS FOR GRANTING THE PETITION

I. The Court Should Grant Review to Correct Florida's Rejection of Impossibility Conflict Pre-emption in a Case Where, Unlike the NDA Regulatory Scheme, the OTC Final Monograph Regulatory Regime Does Not Contain a Provision that Would Allow a Product Manufacturer to Unilaterally Change its Product Labeling by Adding Warnings that Were Not Approved by the FDA.

The doctrine of conflict pre-emption is triggered when compliance with both state and federal law is impossible because one requires what the other prohibits. *Florida Avocado Growers v. Pault*, 373 U.S. 132, 142-143 (1963). In other words, "a case of impossibility" conflict pre-emption is one in which "state law penalizes what federal law requires." *Geier v. American Honda Motor Co.*, 529 U.S. 861, 873 (2000). Here, federal law requiring McNeil's product labeling to use the exact warnings set forth in a Final Monograph irreconcilably conflicts with state law that, according to Respondents, would require McNeil to unilaterally provide additional warnings.

The FDA's Final Monograph establishing the conditions under which nasal decongestants containing pseudoephedrine are generally recognized as "safe and effective and not misbranded" is published at 59 Fed. Reg. 43386 and the warning label requirements are set forth in 21 C.F.R. § 341.80(c)(1). The federal regulation established by the FDA sets forth the mandatory labeling

requirement for *all* manufacturers of *all* products encompassed by the Final Monograph, App. 54a-68a. It is undisputed that McNeil complied. The additional warnings proposed by Respondents are illegal because they are not in compliance with the mandatory labeling language codified in section 341.80(c).

Moreover, the additional warnings urged by Respondents are "different from, in addition to and are not otherwise identical to" those set forth in the applicable Final Monograph. 21 U.S.C. § 379r (providing for national uniformity for non-prescription drugs). In *Wyeth,* the Court noted that product liability actions against an OTC manufacturer are not ***expressly*** pre-empted by section 379r, due to the savings clause contained in section 379r(e). *See Wyeth,* 129 S. Ct. at 1200 n.8. That does not, however, foreclose application of the doctrine of ***implied*** conflict pre-emption. *See Geier,* 529 U.S. at 896-97 (recognizing that an express pre-emption provision coupled with a savings clause does not bar the ordinary working of conflict pre-emption principles).

This point was made in *Dowhal v. SmithKline Beecham Consumer Healthcare,* 88 P.3d 1 (Cal. 2004). In *Dowhal,* a citizen filed an action against various drug companies to challenge their failure to place health warnings mandated by California's Proposition 65 on nicotine replacement therapy (NRT) products. In enacting section 379r, Congress included a specific savings clause to preserve Proposition 65 from the express pre-emptive effect of the statute. *See* 21 U.S.C. § 379r(d)(2) ("This section shall not apply to a State requirement adopted by a State public initiative or ref-

erendum enacted prior to September 1, 1997"). The savings clause was designed to preserve Proposition 65, the only state enactment that fell within its terms. *See Dowhal,* 88 P.3d at 4.

The California Supreme Court held that although the section 379r savings clause precluded ***express*** pre-emption of Proposition 65, it did not preclude application of ***implied*** conflict pre-emption. *Id.* at 9. "The language of the Modernization Act's savings clause does not express an intention to preclude all conflict pre-emption." *Id.* The court recognized that principles of conflict pre-emption would apply if there was a direct conflict between state and federal law or if the state law stood as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. *Id.* at 11.

In this case, the Florida court read *Wyeth* so broadly as to preclude the assertion of implied conflict pre-emption based on impossibility under any circumstances. This case presents a classic example of impossibility. Federal regulations provide for specific warnings and further provide that "any product which fails to conform to an applicable monograph after its effective date is liable to regulatory action." Once a monograph goes into effect, it is illegal to sell a drug described therein unless it conforms to the monograph. *See also* 21 C.F.R. § 330.10(a)(9), 21 U.S.C. §§ 332-334 (providing remedies and penalties for failure to conform). If an OTC product does not comply with a controlling Final Monograph, the United States may bring an enforcement action under FDCA. *See id.* Therefore, it is impossible for McNeil to comply with federal law and also provide the additional

warnings the Respondents are now asking a state court jury in Florida to impose.

In *Wyeth* this Court specifically held that impossibility pre-emption was not available to Wyeth because "the CBE regulation permitted Wyeth to unilaterally strengthen its warning and the mere fact that the FDA approved Phenergan's label does not establish that it would have prohibited such a change." 129 S. Ct. at 1199. Here, by contrast, neither Congress nor the FDA allowed a manufacturer of an OTC product to unilaterally change product warnings that are required to appear verbatim on labeling provided by a manufacturer of a specific category of OTC Final Monograph products.

Without pre-emption, OTC drug manufacturers would be deprived of the ability to rely on FDA's directives as to matters that Congress delegated to the Agency and that fall within the Agency's unique regulatory and scientific expertise. Without pre-emption, McNeil, and all other OTC drug manufacturers, would be deprived of the ability to comply simultaneously with their federal and state obligations or even to ascertain what those obligations are without resort to litigation.

II. The Court Should Grant Review to Resolve the Issue of Whether State Failure-to-Warn Claims Against OTC Final Monograph Drug Manufacturers Stand as an Obstacle to National Uniformity.

This Court has held that "the purpose of Congress is the ultimate touchstone in every pre-emption case." *Wyeth*, 129 S. Ct. at 1187. The his-

torical purpose of the Federal Food, Drug & Cosmetic Act ("FDCA") was to establish a comprehensive scheme of drug regulation to ensure that drugs are safe and effective for their intended use. *See* 21 U.S.C. § 301 *et seq.* The FDA was established as the sole federal agency commissioned both to "protect the public health" by ensuring that drugs are safe and effective and to "promote the public health" by ensuring prompt public access to drugs it has found to be safe and effective. 21 U.S.C. § 393(b). The mechanisms Congress put in place to accomplish the goals of safety and efficacy for nonprescription drugs further illustrate how Congress went about achieving national uniformity.

The FDA Modernization Act of 1997 is codified at 21 U.S.C. section 379r, entitled "National Uniformity for Nonprescription Drugs." The title of the section leaves no doubt that Congress sought uniformity in the regulation of nonprescription drugs. *See, e.g., INS v. Nat'l Center for Immigrant's Rights, Inc.*, 502 U.S. 183, 189 (1991) (a section's title can aid in its interpretation).

The legislative history of the Modernization Act further demonstrates Congress's fundamental purpose of achieving national uniformity by recognizing that "[d]ifferent or additional requirements at the state or local level can work against our national marketplace, confuse consumers, raise prices, undermine confidence in our regulatory system and in products important to public health and result in different public health protection throughout the country." S. Rep. No. 105-43, at 64 (1997).

The goal of national uniformity is apparent from the various statutes and implementing regulations that govern the categories of OTC products, which must have identical labeling regardless of manufacturer. Unlike the NDA regulatory scheme, which focuses on a single drug by a single manufacturer, the Final Monograph regime provides for grouping OTC medications by class or therapeutic category. *See* 21 C.F.R § 330.5 (OTC drug categories). The FDA studies and approves the *category* or *class* of drug, rather than a specific brand or a single drug, as with an NDA. The FDA recognized that hundreds of thousands of OTC products were on the market and would continue to be marketed. Thus, the FDA determined that OTC products using the same active ingredient(s) should have the same labeling requirements.

The regulations that apply to OTC products stand in stark contrast to the regulations applicable to brand-name drugs. First, the NDA process begins when a single manufacturer submits its application for approval to the FDA for its unique drug. Conversely, the Final Monograph process begins with notice-and-comment rulemaking. Here, the FDA Commissioner published a request in the Federal Register seeking data and information on all cold, cough, allergy, bronchodilator and antiasthmatic active ingredients. Procedures for Classification of Over-the-Counter Drugs, 37 Fed. Reg. 9464 (1972); Over-the-Counter Cold, Allergy, Bronchodilator and Antiasthmatic Drug Products, 37 Fed. Reg. 16029.

Second, under the NDA regime, the manufacturer of a single unique product has the burden of proving that its drug is "safe for use under the

conditions prescribed, recommended or suggested in the proposed labeling before it may distribute the drug." 21 U.S.C. § 355; 21 C.F.R. § 314.125. By contrast, the OTC Final Monograph regime does not place this burden on the manufacturers. The FDA appoints an advisory review panel of qualified experts to evaluate the safety and effectiveness of a "designated category of drugs." 21 C.F.R. § 330.10(a)(1); *see also Weinberger*, 412 U.S. at 650. The panel then investigates the drug category, "reviews all available data" and reports its "conclusions and recommendations to the FDA" with respect to the safety and effectiveness of the drugs in the category. 21 C.F.R. § 330.10(a)(3).

Third, under the NDA regime the manufacturer of a single unique product has the burden of providing substantial evidence that its drug will have the effect it is represented to have under the conditions of use prescribed, recommended or suggested in the manufacturer's proposed labeling. *See* 21 U.S.C. § 355; 21 C.F.R. § 314.125. By contrast, manufacturers of OTC Final Monograph drugs are not required to introduce evidence proving safety, effectiveness, or conditions of use. Manufacturers of OTC Final Monograph drugs are not required to test, study, investigate or participate in the regulatory process. The only requirement placed on manufacturers of an FDA OTC Final Monograph product is to follow the Final Monograph.

The OTC Final Monograph regime charges the FDA with preparing a proposed monograph "prescribing drug composition, labeling, and manufacturing controls," publishing it in the Federal Register for comments and considering any addi-

tional data that is submitted before publishing a tentative Final Monograph in the Federal Register. 21 C.F.R. § 330.10(a)(6),(7). After publication of the tentative Final Monograph, the FDA again considers comments and conducts an oral hearing if there are "reasonable grounds" for doing so. 21 C.F.R. § 330.10(a)(8). Then, "after reviewing [any] objections, the entire administrative record including all new data and information and comments, and considering the arguments made at any oral hearing," the FDA publishes in the Federal Register a Final Monograph "establishing conditions under which a category of OTC drugs is generally recognized as safe and effective and not misbranded." 21 C.F.R. § 330.10(a)(9). In this case, the FDA Final Monograph applicable to Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human use is codified at 21 C.F.R. Part 341.

Fourth, under the NDA regime the manufacturer is specifically charged with drafting an adequate label and ensuring that its warnings remain adequate as long as its drug is on the market. *See* 21 C.F.R. § 201.80(e). Under this regime, the FDA promulgated a "changes being effected" (CBE) regulation. 21 C.F.R. § 314.70(c)(6)(iii). The CBE regulation provides that if a manufacturer changes its label to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product," it may make the labeling change upon filing a supplemental application with the FDA; it need not wait for FDA approval. § 314.70 (c)(6)(iii)(A), (C). The *Wyeth* Court found that this provision made it possible

for an NDA manufacturer to change the warning on its label without violating federal law. *Wyeth*, 129 S. Ct. at 1196-1199.

The omission of a CBE regulation in the OTC Final Monograph regulatory regime serves national uniformity. No manufacturer is permitted to change the warning because the warning is not "its" warning for "its" unique product. The FDA's codified warnings apply to entire categories of products produced by many different manufacturers. Allowing unilateral changes to the warning language required by a Final Monograph would destroy national uniformity and undermine public safety.

The *Wyeth* majority specifically recognized that "some state-law claims might well frustrate the achievement of congressional objectives." *Id.* at 1204. Justice Breyer noted in his concurring opinion that there were circumstances where a plaintiff's inadequate warnings claim under "state tort law" would "interfere with the FDA's desire to create a drug label containing a specific set of cautions and instructions." *Id.* at 1204 (Breyer, J., concurring). Accordingly, this Court should take the opportunity to clarify whether state-law requirements for additional warnings on OTC products subject to a Final Monograph would stand as an obstacle to accomplishing the goal of national uniformity.

III. The Court Should Grant Review to Clarify the Confusion Stemming from Overbroad Applications of *Wyeth v. Levine* by Lower Courts.

Some lower courts have given an overly-broad application to *Wyeth* by applying the decision to regulatory schemes other than the NDA process for brand-name drugs. The decisions have used sweeping language stating that the *Wyeth* decision applies to all OTC drugs. That is what the Florida court did in this case. Another example is the Seventh Circuit's decision in *Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861 (7th Cir. 2010). *Robinson* relied on *Wyeth v. Levine* for the proposition that a court is not barred "from holding that state law requires warnings on the label of an over-the-counter drug beyond what the FDA has required." *Id.* at 869.

The *Robinson* court relied upon decisions involving prescription drugs. *See Mason v. SmithKline Beecham Corp.*, 596 F.3d 387 (7th Cir. 2010) (involving the brand-name drug Paxil for treatment of depression); *Demahy v. Actavis*, 593 F.3d 428 (5th Cir. 2010) (involving a generic drug used for the treatment of heartburn). The decisions did not involve OTC drugs subject to Final Monographs.

This Court's decision in *Wyeth* left open the question of pre-emption with regard to drugs, such as the OTC drugs at issue here, which are subject to specific federal labeling regulations. As the Court stated in *Wyeth*, "we have no occasion in this case to consider the pre-emptive effect of a specific agency regulation bearing the force of law." 129 S. Ct. at 1203. By contrast, this case

presents just such an occasion. McNeil's products and their labeling had to comply with specific FDA regulations bearing the force of law and mandating the exact language to be used on the products' labeling.

In *Wyeth*, Justice Breyer concurred to emphasize the Court's statement that "we have no occasion in this case to consider the pre-emptive effect of a specific agency regulation bearing the force of law." *Id.* at 1204 (Breyer, J. concurring). As Justice Breyer recognized, it is "possible that state tort law will sometimes interfere with the FDA's desire to create a drug label containing a specific set of cautions and instructions." *Id.* That is exactly the situation presented by the conflict between Respondent's state-law failure-to-warn claims and the Final Monograph regime which required McNeil to place a specific set of cautions and instructions on its product.

Accepting review will allow this Court to answer the important pre-emption question left open by *Wyeth* by determining whether specific FDA regulations that require OTC drug manufactures to comply with the labeling requirements of Final Monographs pre-empt state law failure-to-warn claims. Accepting review would provide an opportunity for this Court to resolve the confusion created by lower courts that have given an overly-broad application to *Wyeth*.

CONCLUSION

For the foregoing reasons, this Court should grant the petition for a writ of certiorari.

Respectfully submitted,

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Dated: November 30, 2010

APPENDIX

THIRD DISTRICT COURT OF APPEAL
STATE OF FLORIDA, JULY TERM, A.D. 2009

Opinion filed December 30, 2009.
Not final until disposition of timely filed motion for rehearing.

No. 3D08-1563
Lower Tribunal No. 03-9855

ARMANDO VALDES, III, ETC, ET AL.,

Appellants,

—vs.—

OPTIMIST CLUB OF SUNILAND, INC., ET AL.,

Appellees.

An Appeal from the Circuit Court for Miami-Dade County, Daryl W. Trawick, *Judge*.

Hersch & Talisman and Patrice A. Talisman; Donna B. Michelson, and Phillip D. Parrish, *for appellants*.

Thornton, Davis & Fein and Barry L. Davis and Michael D. Bon, *for appellees*.

Before RAMIREZ, C.J., and ROTHENBERG, and LAGOA, JJ.

RAMIREZ, C.J.

Amando Valdes, III and his parents, appeal the trial court's entry of final summary judgment in favor of the defendants below, McNeil-P.P.C., Inc. Because we believe the United States Supreme Court's decision in *Wyeth v. Levine*, 129 S.Ct. 1187 (2009), controls the issue of federal preemption presented in this case, we reverse the trial court's determination.

On April 24, 1999, Armando Valdes, III collapsed during a roller hockey game. He had to be resuscitated at the scene and was then taken to a hospital. Doctors diagnosed him with having suffered a heat stroke and cardio-respiratory arrest which resulted in a brain injury, hypoxic ischemic encephalopathy, and left him completely disabled. On the morning of his collapse, Armando took Tylenol Cold, an over-the-counter medication, for his head cold along with soda. Armando and his parents filed a negligence and products liability suit against McNeil, the manufacturer of Tylenol Cold, as well as the hockey club and equipment vendor, for Armando's injuries.

The Valdeses settled with all the defendants except for defendant McNeil for strict liability and negligent failure to warn. The Valdeses contended that the Tylenol Cold medication, which contains pseudoephedrine, increased the risk of heat-related illness and heart-related risks when ingested with caffeinated products and coupled with strenuous or athletic events in a hot envi-

ronment like that of South Florida. They asserted that McNeil's failure to warn of these risks on the labels of the Tylenol Cold packaging breached Florida state law requirements.

McNeil filed several affirmative defenses in its response to the Valdeses' complaint including federal preemption. After discovery, McNeil moved for final summary judgment arguing that federal law, which governs over-the-counter and non-prescription drugs, and the FDA's labeling requirements, which did not require McNeil to include the risk of heat-related illness on the label, preempted the state law claims in the Valdeses' complaint, 21 U.S.C. § 379r. The lower court agreed and granted final summary judgment in favor of McNeil. The Valdeses appealed the decision to this Court.

Because this is an appeal from an order of summary judgment and calls for a review of an issue of law, our standard of review is *de novo, State v. Coney,* 845 So. 2d 120, 137 (Fla. 2003).

McNeil argues that federal law that governs the labeling of medication preempts state law requirements and bars state law claims from being brought against it since its label contained the FDA-approved language. The federal statute in question states that no State or political subdivision thereof may establish regulations for drugs different from those required by that chapter of the statute unless one of the listed statutory exceptions applies, 21 U.S.C. § 379r(b). The exception at issue, subsection (e), states: "[n]othing in this section shall be constituted to modify or otherwise affect any action or the liability of any person under the product liability law of any State." 21 U.S.C. § 379r(e). McNeil concedes that express

preemption does not apply, but argues that implied preemption is applicable here because compliance with both state law and federal law is impossible and, even if not impossible, would frustrate the Congressional purposes and objectives behind the enactment of the statute.

The Court recently decided *Wyeth*, and the ruling in that case controls our decision here. *See Wyeth v. Levine*, 129 S.Ct. 1187 (2009). The facts in *Wyeth* are similar to the ones here, and the arguments made by the prescription drug manufacturer are practically identical to those advanced by McNeil. In *Wyeth*, the Court found that:

> If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history. But despite its 1976 enactment of an express pre-emption provision for medical devices . . . , Congress has not enacted such a provision for prescription drugs . . . Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.

Id. at 1200.

McNeil argues that *Wyeth* is distinguishable because it dealt with prescription drugs and not over-the-counter medication like those at issue here. We disagree with McNeil that the distinction

carries the weight to allow it to circumvent the reasoning of the Court in *Wyeth*. After extensively detailing the historical background of the FDCA and amendments to the act, the Court found that the failure of Congress to expressly preempt the field in light of the long history since enacting the FDA leads to the conclusion that state actions like those here "lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times. Thus, the FDA long maintained that state law offers an additional, and important, layer of consumer protections that complements the FDA regulation." *Id.* at 1202-03. Additionally, the Court, citing to the very statutory exception at issue here, stated in a footnote that the 1997 amendment to the statute "pre-empted certain state requirements concerning over-the-counter medications and cosmetics but expressly preserved product liability actions. *See* 21 U.S.C. §§ 379r(e), 379s(d)." *Id.* at 1200 n.8. This further weakens McNeil's attempts to distinguish *Wyeth* from the facts of this case.

Based on the Court's holding in *Wyeth*, we conclude that the trial court's entry of final summary judgment in McNeil's favor was in error and therefore reverse. The federal law that regulates the labels of over-the-counter medication at issue here expressly saves this type of state law causes of action, and there is no implied federal preemption that would keep the Valdeses from going forward with their suit against McNeil.

Reversed.

IN THE DISTRICT COURT OF APPEAL
OF FLORIDA
THIRD DISTRICT
JANUARY TERM, A.D. 2010
FEBRUARY 23, 2010

Case No.: 3D08-1563

Lower Tribunal No. 03-9855

ARMANDO VALDES, III, ETC, ET AL.,

Appellant(s)/Petitioner(s),

—VS.—

OPTIMIST CLUB OF SUNILAND, INC., ET AL.,

Appellee(s)/Respondent(s).

Upon consideration, appellee McNeil-P.P.C., Inc.'s motion for rehearing and clarification is hereby denied. RAMIREZ, C.J., and ROTHENBERG and LAGOA, JJ., concur. Appellee McNeil-P.P.C., Inc.'s motion for rehearing en banc is hereby denied.

[SEAL]

cc:
David Rutherford
Edward F. Gagain, III
Donna B. Michelson
Philip D. Parrish
Stephen W. Bazinsky
Barry L. Davis

SUPREME COURT OF FLORIDA

Monday, August 2, 2010

Case No.: SC10-557
Lower Tribunal No(s).: 3D08-1563, 03-09855

MCNEIL P.P.C., INC.,
Petitioner(s)

—vs.—

ARMANDO VALDES, III, ETC., ET AL.,
Respondent(s)

This cause having heretofore been submitted to the Court on jurisdictional briefs and portions of the record deemed necessary to reflect jurisdiction under Article V, Section 3(b), Florida Constitution, and the Court having determined that it should decline to accept jurisdiction, it is ordered that the petition for review is denied.

No motion for rehearing will be entertained by the Court. *See* Fla. R. App. P. 9.330(d)(2).

PARIENTE, QUINCE, POLSTON, LABARGA and PERRY, JJ., concur.

A True Copy
Test:

/s/ THOMAS D. HALL
Thomas D. Hall [SEAL]
Clerk, Supreme Court

wm
Served:

BARRY L. DAVIS
PHILIP DIXON PARRISH
DONNA B. MICHELSON
HON. HARVEY RUVIN, CLERK
HON. MARY CAY BLANKS, CLERK
HON. DARYL E. TRAWICK, JUDGE

IN THE CIRCUIT COURT OF THE
11TH JUDICIAL CIRCUIT IN AND FOR
MIAMI-DADE COUNTY, FLORIDA

GENERAL JURISDICTION DIVISION

Case No. 03-09855 CA 20

ARMANDO VALDES, III, incapacitated, by and through his legal guardians, ARMANDO VALDES, JR. and VIOLETTA VALDES, and ARMANDO VALDES, JR. and VIOLETTA VALDES, individually,

Plaintiffs,

—v.—

OPTIMIST CLUB OF SUNILAND, INC., OPTIMIST INTERNATIONAL, MCNEIL-P.P.C., THE SPORTS AUTHORITY, INC., JOFA AB, KHF SPORTS OY, and THE HOCKEY COMPANY,

Defendant(s).

ORDER GRANTING DEFENDANT, MCNEIL-P.P.C., INC.'S MOTION FOR FINAL SUMMARY JUDGMENT

THIS CAUSE came on to be heard on April 28, 2008 on Defendant, McNeil-P.P.C., Inc.'s Motion for Final Summary Judgment, and the Court having heard argument of counsel, having reviewed

the motion and memoranda submitted by the parties, and being otherwise duly advised in the premises, it is hereupon

ORDERED and ADJUDGED that said Motion is hereby **GRANTED**. This Court finds that there are no genuine issues of material fact in dispute and that McNeil-P.P.C., Inc. ("McNeil") is entitled to judgment as a matter of law. Plaintiffs' claim against McNeil—both of which are based upon failure-to-warn/inadequate warnings—are preempted by federal law. The Plaintiffs' claims are expressly preempted by 21 U.S.C. § 379r (entitled, *"National Uniformity for Nonprescription Drugs)* which specifically prohibits states, through a jury verdict or otherwise, from establishing or continuing in effect any warning requirement for a final monograph over-the-counter drug that is "different from or in addition to, or that is otherwise not identical with" those required under federal law. Although 21 U.S.C. § 379r(e) contains a savings clause, reading the savings clause herein to exclude the preemption of lawsuits premised on inadequate labeling or failure-to-warn (as Plaintiffs suggest) would make the express preemption provisions of 21 U.S.C. § 397r(a) a nullity and would presume that Congress included superfluous provisions or otherwise engaged in an idle act when it enacted this statute. The United States Supreme Court has determined that it is a fundamental principle that a savings clause should not be interpreted in such a way as to undercut or dilute an express preemption clause. *See American Tel. and Tel. Co. v. Central Office Telephone, Inc.*, 524 U.S. 214, 228, 118 S.Ct. 1956, 141 L.Ed.2d

222 (1998). "In other words, the act cannot be held to destroy itself." *Id. quoting Texas & Pacific R. Co. v. Abilene Cotton Oil Co.*, 204 U.S. 426, 446, 27 S.Ct. 350, 358, 51 L.Ed. 553 (1907).

Additionally, as also stated by the United States Supreme Court, an express preemption provision coupled with a savings clause does not, by "negative implication" or otherwise, "bar the ordinary working of conflict preemption principles." *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 869, 120 S.Ct. 1913, 146 L.Ed.2d 914 (2000). As the non-prescription drug product at issue here is one that is governed by specific mandatory warnings set forth in a Final Monograph, both forms of implied conflict preemption apply: (a) impossibility and (b) frustration-of-purpose: Accordingly, final summary judgment in favor of McNeil and against Plaintiffs is warranted under each of these preemption doctrines.

DONE AND ORDERED in Chambers, at Miami, Miami-Dade County, Florida, this 14th day of May, 2008.

/s/ HON. DARYL E. TRAWICK
HON. DARYL E. TRAWICK
Circuit Court Judge

Copies furnished to all parties listed on the attached service list

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IN THE CIRCUIT COURT OF THE
11TH JUDICIAL CIRCUIT IN AND FOR
MIAMI-DADE COUNTY, FLORIDA

GENERAL JURISDICTION DIVISION

Case No. 03-09855 CA 20

ARMANDO VALDES, III, incapacitated, by and through his legal guardians, ARMANDO VALDES, JR. and VIOLETTA VALDES, and ARMANDO VALDES, JR. and VIOLETTA VALDES, individually,

Plaintiffs,

—v.—

OPTIMIST CLUB OF SUNILAND, INC., OPTIMIST INTERNATIONAL, MCNEIL-P.P.C., THE SPORTS AUTHORITY, INC., JOFA AB, KHF SPORTS OY, and THE HOCKEY COMPANY,

Defendant(s).

FINAL SUMMARY JUDGMENT FOR DEFENDANT MCNEIL-P.P.C., INC.

THIS CAUSE having come before the Court on Defendant, McNeil-P.P.C., Inc.'s Motion for Entry of Final Summary Judgment following this Court's entry of the May 14, 2008 *Order Granting Defen-*

dant, McNeil-P.P.C., Inc.'s Motion for Final Summary Judgment and this Court, having reviewed the motion and being otherwise fully advised in the premises, it is hereupon

ORDERED and ADJUDGED that Final Summary Judgment is hereby entered in favor of Defendant McNeil-P.P.C., Inc. and against Plaintiffs. Plaintiffs, ARMANDO VALDES, III, by and through his legal guardians, ARMANDO VALDES, JR. and VIOLETTA VALDES, and ARMANDO VALDES, JR. and VIOLETTA VALDES, individually, take nothing by this action and that Defendant, McNeil-P.P.C., Inc., shall go hence without day.

DONE AND ORDERED in Chambers, at Miami, Miami-Dade County, Florida, this 9th day of June, 2008.

/s/ HON. DARYL E. TRAWICK
HON. DARYL E. TRAWICK
Circuit Court Judge

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IN THE CIRCUIT COURT OF THE
11TH JUDICIAL CIRCUIT IN AND
FOR DADE COUNTY, FLORIDA

GENERAL JURISDICTION DIVISION

Case No. 03-09855 CA 20

Filed April 23, 2003

ARMANDO VALDES, III, incapacitated, by and through his legal guardians, ARMANDO VALDES, JR. and VIOLETTA VALDES, and ARMANDO VALDES, JR. and VIOLETTA VALDES, individually,

Plaintiffs,

—VS.—

OPTIMIST CLUB OF SUNILAND, INC., OPTIMIST INTERNATIONAL, MCNEIL-P.P.C., THE SPORTS AUTHORITY, INC., JOFA AB, KHF SPORTS OY, and THE HOCKEY COMPANY,

Defendants.

COMPLAINT

Plaintiffs, ARMANDO VALDES, III, incapacitated, by and through his legal guardians, ARMANDO VALDES, JR. and VIOLETTA VALDES, and ARMANDO VALDES, JR. and VIOLETTA VALDES, individually, sue Defendants, OPTIMIST CLUB OF SUNILAND, INC. OPTIMIST INTERNATIONAL, MCNEIL-P.P.C., INC., THE SPORTS AUTHORITY, INC., JOFA AB, KHF SPORTS OY, and THE HOCKEY COMPANY, and allege:

1. This is a cause of action for damages in excess of $15,000.00 exclusive of interest and costs.

2. As a result of the incident which forms the basis of this lawsuit, Plaintiff, ARMANDO VALDES, III, a resident of Miami-Dade County, Florida, whose date of birth is March 15, 1983, is legally incapacitated.

3. At all times material, Plaintiffs, ARMANDO VALDES, JR. and VIOLETTA VALDES, were and are the natural parents and legal guardians of ARMANDO VALDES, III, incapacitated; residents of Miami-Dade County, Florida; over the age of 18 years; and otherwise sui juris.

4. At all times material, Defendant, OPTIMIST CLUB OF SUNILAND, INC. (hereinafter "SUNILAND OPTIMISTS"), now dissolved, was a Florida non-profit corporation with its principal place of business in Miami-Dade County, Florida. Among other things, said Defendant was regularly engaged in the business of operating, controlling and conducting athletic events and sports leagues, including a roller hockey league. Said Defendant was

chartered as a member Club of Defendant, OPTIMIST INTERNATIONAL.

5. At all times material, Defendant, OPTIMIST INTERNATIONAL, a foreign non-profit corporation with its principal place of business in St. Louis, Missouri, was in the business of affiliating Clubs to, among other things, sponsor, operate, control and conduct athletic events and sports leagues. Said Defendant was regularly engaged in said business in the State of Florida through its agents, its chartered member Clubs, including Defendant, SUNILAND OPTIMISTS, as it directed the programs and established the policies for its member Clubs and required them to comply with its directives and policies. As a result, said Defendant was operating, conducting, engaging in and carrying on business in the State of Florida and it was that activity which gave rise to Plaintiff, ARMANDO VALDES, III's, injury.

6. Defendant, MCNEIL-P.P.C., INC. (hereinafter "MCNEIL"), was a foreign corporation transacting business within the State of Florida for profit and the cause of action which is hereinafter alleged arose from that business or business venture being carried on by said Defendant. More specifically, at all times material, Defendant MCNEIL, did manufacture Tylenol products, including Tylenol Cold and Tylenol Flu, outside of the State of Florida that were sold into the stream of commerce with the intent and knowledge that such products would ultimately be utilized in the State of Florida, wherein any defects or hazards or breaches of warranties regarding such products

would or might result in injuries, claims and damages.

7. At all times material, Defendant, THE SPORTS AUTHORITY, INC. (hereinafter "SPORTS AUTHORITY"), was a foreign corporation registered to and, in fact doing business in the State of Florida with its principal place of business located at 3383 N. State Road 7, Ft. Lauderdale, Florida. Said Defendant was in the business of marketing and selling sports equipment to the general public and did have numerous stores in the State of Florida, including several in Miami-Dade County, Florida.

8. Defendant, JOFA AB (hereinafter "'JOFA"), was a foreign corporation transacting business within the State of Florida for profit and the cause of action, which is hereinafter alleged, arose from that business or business venture being carried on by said Defendant. At all times material, Defendant, JOFA, did manufacture and or distribute hockey gear, including helmets, outside of the State of Florida that was sold into the stream of commerce with the intent and knowledge that such goods would ultimately be utilized in the State of Florida, wherein any defects or hazards or breaches of warranties regarding such goods would or might result in injuries, claims and damages. More specifically, prior to April 24, 1999, Defendant, JOFA, did design, manufacture and or distribute JOFA brand helmets for ice hockey, which were then distributed and or sold by said Defendant to Defendant, SPORTS AUTHORITY, for retail sale to the public for use in both ice hockey

and roller hockey and Plaintiffs purchased one of those helmets.

9. Defendant, KHF SPORTS OY (hereinafter "KHF SPORTS"), was a foreign corporation transacting business within the State of Florida for profit and the cause of action, which is hereinafter alleged, arose from that business or business venture being carried on by said Defendant. At all times material, Defendant, KHF SPORTS, did manufacture and/or distribute hockey gear, including gloves, outside of the State of Florida that was sold into the stream of commerce with the intent and knowledge that such goods would ultimately be utilized in the State of Florida, wherein any defects or hazards of breaches of warranties regarding such goods would or might result in injuries, claims and damages. More specifically, prior April 24, 1999, Defendant, KHF SPORTS, did design, manufacture and/or distribute KOHO brand gloves for ice hockey, which were then distributed and/or sold by said Defendant to Defendant, SPORTS AUTHORITY, for retail sale to the public for use in both ice hockey and roller hockey and Plaintiffs purchased one of those pairs of gloves.

10. Defendant, THE HOCKEY COMPANY, was a foreign corporation transacting business within the State of Florida for profit and the cause of action, which is hereinafter alleged, arose from that business or business venture being carried on by said Defendant. At all times material, Defendant, THE HOCKEY COMPANY, did manufacture and/or distribute hockey gear, including helmets and gloves, outside of the State of Florida that

was sold into the stream of commerce with the intent and knowledge that such goods would ultimately be utilized in the State of Florida, wherein any defects or hazards or breaches of warranties regarding such goods would or might result in injuries, claims and damages. More specifically, prior to April 24, 1999, Defendant, THE HOCKEY COMPANY, did design and manufacture helmets and gloves for ice hockey. Said Defendant did then distribute said helmets and gloves to Defendants, JOFA and KHF SPORTS, respectively, for marketing and sale to retailers and the public for use in both ice hockey and roller hockey. Alternatively, Defendants, JOFA and KHF SPORTS, respectively, designed and manufactured helmets and gloves and Defendant, THE HOCKEY COMPANY, acted as their agent with respect to sales and distribution of said products within the United States, including within Florida. Said helmets and gloves were sold to Defendant, SPORTS AUTHORITY, who in turn sold one of the JOFA brand helmets and one of the KOHO brand pairs of gloves to the Plaintiffs.

11. Prior to April 24, 1999, Plaintiffs, ARMANDO VALDES, JR. and VIOLETTA VALDES, did, without joining SUNILAND OPTIMISTS, sign up their son, ARMANDO VALDES, III, then a minor, as a participant in the SUNILAND OPTIMISTS' Youth Roller Hockey League. They paid the non-club member fee for their son's participation in the league.

12. Prior to April 24, 1999, Plaintiff, ARMANDO VALDES, III, accompanied by one or both of his parents, did go to Sports Authority stores owned by Defendant, SPORTS AUTHORITY, to shop for and

purchase equipment and gear for his use in the SUNILAND OPTIMISTS' Roller Hockey League. On one or more of those occasions, said Plaintiffs, upon entering the store, asked for roller hockey equipment and gear and were directed by Defendant, SPORTS AUTHORITY's, employees to the area of the store designated for Hockey. Unappreciated by the Plaintiffs was the fact that, the hockey gear in that area was actually designed for ice hockey use and not for roller hockey use. Plaintiffs resultingly purchased a JOFA brand helmet and KOHO brand gloves from Defendant's stores, which subjected Plaintiff, ARMANDO VALDES, III, to a greater risk of heat stroke because the insulation prevented his body's normal heat dissipation through the head and hands.

13. Prior to April 24, 1999, Defendant, SUNILAND OPTIMIST, through its employees and/or agents, did schedule a game for Plaintiff, ARMANDO VALDES, III's, youth roller hockey team for April 24, 1999, at approximately 1:00 p.m. at the Palmetto Golf Course Roller Hockey Rink where there were no adequate shaded areas for the participants.

14. On the morning of April 24, 1999, Plaintiff, ARMANDO VALDES, III, was feeling symptoms of a head cold or flu and decided to take a cold or flu medication prior to the game. Plaintiff took Tylenol Cold or Tylenol Flu medication manufactured by Defendant, MCNEIL, containing pseudoephedrine, which Plaintiff, VIOLETTA VALDES, had previously purchased for the family's use. It is also likely that Plaintiff drank a caffeinated soda that day prior to the game as well.

15. On April 24, 1999, Plaintiff, ARMANDO VALDES, III attended and participated in his team's roller hockey game at the Palmetto Golf Course Roller hockey rink. Said game took place at approximately noon or 1:00 p.m. with the temperature in the 80's (degrees Fahrenheit). At said time and place, Plaintiff wore his uniform as well as required gear including his helmet and gloves.

16. At said time and place, because the team was shorthanded, Plaintiff, ARMANDO VALDES, III, played most of the game.

17. At said time and place, as the game was nearing completion, Plaintiff, ARMANDO VALDES, III, collapsed while on the rink due to heat stroke. Plaintiff, ARMANDO VALDES, III, suffered a cardiorespiratory arrest which left him permanently and significantly brain damaged.

COUNT I—NEGLIGENCE OF DEFENDANT, SUNILAND OPTIMISTS

Plaintiffs repeat and adopt paragraphs 1 through 17 above and further allege:

18. At all times material, Defendant, SUNILAND OPTIMISTS, as sponsor and operator of a youth roller hockey league, through its employees and/or agents, had the obligation to operate, control and conduct said league in a non-negligent way and to take reasonable precautions to prevent heat illness in its youth athletic participants.

19. Notwithstanding the above, Defendant, SUNILAND OPTIMISTS, acting through its employ-

ees and/or agents, was negligent in the commission or omission of the following acts:

a. chose a facility at which to play its roller hockey games that was without adequate shaded areas;

b. scheduled Plaintiff's team's game for the heat of the day in April, a month that is both hot and humid in South Florida;

c. failed to have in effect and/or to enforce reasonable policies and procedures for heat illness prevention such as, among other ways, limiting the participants' playing time, requiring the participants to remove gear during rest periods to allow for heat dissipation, providing shaded areas for appropriate rest periods, scheduling games at cooler times of day and providing adequate hydration sources;

d. failed to recommend and/or provide roller hockey gear suitably colored, ventilated and otherwise appropriate to be used in the heat and humidity of South Florida;

e. failed to have a properly trained Commissioner and/or Coaches on the subject of heat illness prevention;

f. failed to warn the league participants of the risk of heat illness and, particularly, heat stroke and to instruct said participants on how to minimize the risks: and

g. other acts that will be learned of through discovery.

20. As a direct and proximate result of the above-described negligence, Plaintiff, ARMANDO VALDES, III, incapacitated, suffered heat stroke resulting in bodily injury, including brain damage, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, loss of capacity for the enjoyment of life, the expense of hospitalization, medical and nursing care and treatment, and loss of wage earning capacity. The injuries are permanent in nature and Plaintiff will suffer these losses in the future.

21. As a further direct and proximate result, Plaintiffs, ARMANDO VALDES, JR. and VIOLETTA VALDES, individually, have incurred the expense of their son's hospitalization, medical and nursing care and treatment and have suffered the loss of their son's companionship, society, love, affection, and solace as well as loss of ordinary day-to-day services he would have rendered. Plaintiffs will suffer these losses in the future.

COUNT II—NEGLIGENCE OF OPTIMIST INTERNATIONAL

Plaintiffs repeat and adopt paragraphs 1 through 17 above and further allege:

22. At all times material, Defendant, OPTIMIST INTERNATIONAL, through its agents, its affiliated member Clubs, did sponsor, conduct and operate athletic events and sports leagues. Said Defendant did provide directives and policies to its member Clubs, including Defendant, SUNILAND OPTI-

MISTS, concerning the manner and methods of sponsoring, conducting and operating athletic events and sports leagues.

23. At all times material, Defendant, OPTIMISTS INTERNATIONAL, had an obligation, to use reasonable care in overseeing the activities of its member Clubs and to assure that they took reasonable precautions to prevent heat illness at their events and league games, particularly the children and youth leagues.

24. Notwithstanding the above, Defendant, OPTIMIST INTERNATIONAL, acting through its employees and/or agents, was negligent in the commission or omission of the following acts regarding the operation of its roller hockey leagues:

a. failed to have in effect and to enforce reasonable policies and procedures for heat illness prevention such as, among other ways, limiting the participants' playing time, requiring the participants to remove gear during rest periods to allow for heat dissipation, providing shaded areas for appropriate rest periods, scheduling games at cooler times of day and providing adequate hydration sources;

b. failed to recommend and/or provide roller hockey gear suitably colored, ventilated and otherwise appropriate to be used in hot and humid climates;

c. failed to establish heat illness prevention guidelines for use by its mem-

ber clubs to train and instruct the club's Commissioners and/or Coaches; and

d. other acts that will be learned of through discovery.

25. As a direct and proximate result of the above-described negligence. Plaintiff, ARMANDO VALDES, III, incapacitated, suffered heat stroke resulting in bodily injury, including brain damage, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, loss of capacity for the enjoyment of life, the expense of hospitalization, medical and nursing care and treatment, and loss of wage earning capacity. The injuries are permanent in nature and Plaintiff will suffer these losses in the future.

26. As a further direct and proximate result, Plaintiffs, ARMANDO VALDES, JR. and VIOLETTA VALDES, individually, have incurred the expense of hospitalization, medical and nursing care and treatment and have suffered the loss of their son's companionship, society, love, affection, and solace as well as loss of ordinary day-to-day services he would have rendered. Plaintiffs will suffer these losses in the Future.

COUNT III—STRICT LIABILITY OF MCNEIL

Plaintiffs repeat and adopt paragraphs 1 through 17 above and further allege:

27. Prior to April 24, 1999, Plaintiff, VIOLETTA VALDES, purchased Tylenol Cold and Tylenol Flu for the family's use when needed. Unappreciated

by the Plaintiffs, Defendant, MCNEIL's products, Tylenol Cold and Tylenol Flu, contain the decongestant, pseudoephedrine, an ephedrine alkaloid which can produce effects similar to amphetamines. When pseudoephedrine is used in combination with caffeine, stimulant effects are multiplied. Moreover, because one of the effects of pseudoephedrine is to constrict blood vessels, which impairs the body's ability to dissipate heat, this in turn increases the risk of heat illness especially in those participating in athletic events, such as the Plaintiff, ARMANDO VALDES, III.

28. Tylenol Cold and Tylenol Flu were designed, manufactured, assembled, tested, packaged, distributed and sold by Defendant, MCNEIL, in a defective condition unreasonably dangerous to the users, such as Plaintiff, ARMANDO VALDES, III, in that:

a. said medications failed to warn or to adequately warn users of the risks and latent dangers inherent in the use of them in their normal and intended manner, particularly, when users are also ingesting caffeinated products and participating in athletic or strenuous events in a hot climate; and

b. said medications failed to instruct or to adequately instruct users on how and when to use them.

29. Due to the defects described in Paragraph 28, the Tylenol Cold or Tylenol Flu taken by Plaintiff, ARMANDO VALDES, III, which was

designed, manufactured, assembled, tested, packaged, distributed and sold by Defendant MCNEIL, was not reasonably fit for the purposes for which it was intended or for the purposes reasonably foreseeable at the time of its design, manufacture, assembly, packaging, distribution and sale.

30. Due to the defects described in Paragraph 28, the Tylenol Cold or Tylenol Flu taken by Plaintiff, ARMANDO VALDES, III, which was designed, manufactured, assembled, tested, packaged, distributed and sold by Defendant, MCNEIL, was placed on the market in a defective or inherently dangerous condition.

31. Due to the defects described in Paragraph 28, the Tylenol Cold or Tylenol Flu taken by Plaintiff, ARMANDO VALDES, III, was unreasonably dangerous because of its design, manufacture, assembly, testing, packaging, distribution and sale in that the risk of danger to users, such as Plaintiff, outweighed the benefits of the product.

32. Due to the defects described in Paragraph 28, the Tylenol Cold or Tylenol Flu taken by Plaintiff, ARMANDO VALDES, III, was dangerous beyond the expectation of the ordinary user when used as intended or in a manner reasonably foreseeable to the Defendant, MCNEIL.

33. Plaintiffs were unaware of the defective and unreasonably dangerous condition of the Defendant's medications.

34. Defendant, MCNEIL, knew or should have know that its medication would be used without inspection for defects, and by placing it on the

market represented that it would safely do the job for which it was intended.

35. As a direct and proximate result of the defects described above, Plaintiff, ARMANDO VALDES, III, incapacitated, suffered heat stroke resulting in bodily injury, including brain damage, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, loss of capacity for the enjoyment of life the expense of hospitalization, medical and nursing care and treatment, and loss of wage earning capacity. The injuries are permanent in nature and Plaintiff will suffer these losses in the future.

36. As a further direct and proximate result, Plaintiffs, ARMANDO VALDES JR., III and VIOLETTA VALDES, individually, have incurred the expense of their son's hospitalization, medical and nursing care and treatment and have suffered the loss of their son's companionship, society, love, affection, and solace as well as loss of ordinary day-to-day services he would have rendered. Plaintiffs will suffer these losses in the future.

COUNT IV—NEGLIGENCE OF DEFENDANT, MCNEIL

Plaintiffs repeat and adopt paragraphs 1 through 17 and 27 above and further allege:

37. At all times material hereto, Defendant, MCNEIL, had a duty to design, manufacture, assemble, test, package, distribute and sell its medications and to provide warnings to be utilized and relied on by users in a manner that would make said medications, and in particular the med-

ication at issue in this case, reasonably safe for use.

38. At all times material hereto, Defendant, MCNEIL, breached said duties owing to the Plaintiffs by failing to exercise reasonable care in the design, manufacture, assembly, testing, packaging, distribution and sale of the subject medications for the reasons set forth in Paragraph 28.

39. At all times material hereto, Defendant, MCNEIL, knew, or in the exercise of reasonable care should have known, that its acts and omissions with respect to the design, manufacture, assembly, testing, packaging, distribution and sale of the subject medication, together with its lack of warnings, would result in injury to users, such as the Plaintiff, ARMANDO VALDES, III.

40. As a direct and proximate result of the above-described negligence, the subject medication caused the Plaintiff, ARMANDO VALDES, III, to suffer heat stroke resulting in bodily injury, including brain damage, pain and suffering, disability, physical impairments, disfigurement, loss of capacity for the enjoyment of life, the expenses of hospitalization, medical and nursing care and treatment, and loss of wage earning capacity. These injuries are permanent in nature and the Plaintiff will suffer these losses in the future.

41. As a further direct and proximate result, Plaintiffs, ARMANDO VALDES, JR. and VIOLETTA VALDES, individually, have incurred the expense of their son's hospitalization, medical and nursing care and treatment and have suffered the loss of their son's companionship, society, love, affection,

and solace as well as loss of ordinary day-to-day services he would have rendered. Plaintiffs will suffer these losses in the future.

COUNT V—STRICT LIABILITY OF SPORTS AUTHORITY

Plaintiffs repeat and adopt Paragraphs 1 through 17 and further allege:

42. At all times material, Defendant, SPORTS AUTHORITY, was involved in the marketing, distribution and sale of hockey gear to the public. Defendant, SPORTS AUTHORITY, did market, distribute and sell ice hockey gear as roller hockey gear, including the JOFA brand helmet and KOHO brand gloves which were purchased by the Plaintiffs.

43. The JOFA brand helmet and KOHO brand gloves at issue in this case were designed, manufactured, tested, packaged, marketed, distributed and sold by Defendant, SPORTS AUTHORITY, in a defective condition unreasonably dangerous to roller hockey users, such as Plaintiff, ARMANDO VALDES, III, in that:

a. said gear was not adequately ventilated, colored and otherwise appropriate for use in roller hockey in a hot climate;

b. said gear failed to warn or to adequately warn users of the risks and latent dangers inherent in using ice hockey gear for roller hockey in a hot climate; and

c. said gear failed to instruct or to adequately instruct roller hockey users of how and when to use the gear.

44. Due to the defects described in Paragraph 43, the JOFA brand helmet and KOHO brand gloves sold to Plaintiff by Defendant, SPORTS AUTHORITY, were not reasonably fit for the purposes for which they were intended or for the purposes reasonably foreseeable at the time of marketing, distribution and sale by Defendant, SPORTS AUTHORITY.

45. Due to the defects described in Paragraph 43, the JOFA brand helmet and KOHO brand gloves sold to Plaintiff by Defendant, SPORTS AUTHORITY, were placed on the market in a defective or inherently dangerous condition.

46. Due to the defects described in Paragraph 43, the JOFA brand helmet and KOHO brand gloves and sold to Plaintiff by Defendant, SPORTS AUTHORITY, were unreasonably dangerous because the risk of danger to users, such as Plaintiff, ARMANDO VALDES, III, outweighed the benefits of the product.

47. Due to the defects described in Paragraph 43, the JOFA brand helmet and KOHO brand gloves sold to Plaintiff by Defendant, SPORTS AUTHORITY, were dangerous beyond the expectation of the ordinary user when used as intended or in a manner reasonably foreseeable to the Defendant, SPORTS AUTHORITY.

48. Plaintiffs were unaware of the defective and unreasonably dangerous condition of the JOFA

brand helmet and KOHO brand gloves at issue in this case.

49. Defendant, SPORTS AUTHORITY, knew or should have known that its hockey gear would be used without inspection for defects, and by placing it on the market represented that it would safely do the job for which it was intended.

50. As a direct and proximate result of the defects described above, Plaintiff, ARMANDO VALDES, III, incapacitated, suffered heat stroke resulting in bodily injury, including brain damage, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, loss of capacity for the enjoyment of life, the expense of hospitalization, medical and nursing care and treatment, and loss of wage earning capacity. The injuries are permanent in nature and Plaintiff will suffer these losses in the future.

51. As a further direct and proximate result, Plaintiffs, ARMANDO VALDES, JR. and VIOLETTA VALDES, individually, have incurred the expense of their son's hospitalization, medical and nursing care and treatment and have suffered the loss of their son's companionship, society, love, affection, and solace as well as loss of ordinary day-to-day services he would have rendered. Plaintiffs will suffer these losses in the future.

COUNT VI—BREACH OF WARRANTY BY SPORTS AUTHORITY

Plaintiffs repeat and adopt Paragraphs 1 through 17, 42 and 43 and further allege:

52. At all times material, Defendant, SPORTS AUTHORITY, warranted that the hockey gear it sold was reasonably fit for its intended use for all types of hockey, including roller hockey played outdoors in the hot and humid climate of South Florida.

53. Plaintiffs purchased hockey gear from Defendant, SPORTS AUTHORITY, as more specifically described in paragraph 12.

54. Due to the defects described in Paragraph 43, the JOFA brand helmet and KOHO brand gloves sold to Plaintiff by Defendant, SPORTS AUTHORITY, were not reasonably fit for the purposes for which they were intended or for the purposes reasonably foreseeable to Defendant at the time of sale.

55. Due to the defects described in Paragraph 43, the JOFA brand helmet and KOHO brand gloves sold to Plaintiff by Defendant, SPORTS AUTHORITY, were not reasonably fit for the specific purpose for which Defendant, SPORTS AUTHORITY, knowingly sold them and for which Plaintiff bought them in reliance on the judgment of Defendant, SPORTS AUTHORITY.

56. As a direct and proximate result of the breaches described above, Plaintiff, ARMANDO VALDES, III, incapacitated, suffered heat stroke resulting in bodily injury, including brain damage, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, loss of capacity for the enjoyment of life, the expense of hospitalization, medical and nursing care and treatment, and loss of wage earning

capacity. The injuries are permanent in nature and Plaintiff will suffer these losses in the future.

57. As a further direct and proximate result, Plaintiffs, ARMANDO VALDES, JR. and VIOLETTA VALDES, individually, have incurred the expense of their son's hospitalization, medical and nursing care and treatment and have suffered the loss of their son's companionship, society, love, affection, and solace as well as loss of ordinary day-to-day services he would have rendered. Plaintiffs will suffer these losses in the future.

COUNT VII—NEGLIGENCE OF SPORTS AUTHORITY

Plaintiffs repeat and adopt Paragraphs 1 through 17 and 42 and further allege:

58. At all times material, Defendant, SPORTS AUTHORITY, had a duty to market, recommend and sell hockey gear in a reasonably safe manner and to provide warnings to be utilized and relied on by users in a manner that would make said gear, and in particular the gear at issue in this case, reasonably safe for use.

59. At all times material, Defendant, SPORTS AUTHORITY, breached said duties owing to the Plaintiffs by failing to exercise reasonable care in the marketing, recommendation of and sale of the hockey gear at issue in this case for the reasons set forth in Paragraph 43 above.

60. At all times material, Defendant, SPORTS AUTHORITY, knew, or in the exercise of reasonable care, should have known, that its acts and omis-

sions with respect to the marketing, recommendation of and sale of the hockey equipment at issue in this case, together with its lack of warnings and instructions, would result in injury to users such as Plaintiff, ARMANDO VALDES, III.

61. As a direct and proximate result of the above-described negligence, Plaintiff, ARMANDO VALDES, III, incapacitated, suffered heat stroke resulting in bodily injury, including brain damage, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, loss of capacity for the enjoyment of life, the expense of hospitalization, medical and nursing care and treatment, and loss of wage earning capacity. The injuries are permanent in nature and Plaintiff will suffer these losses in the future.

62. As a further direct and proximate result, Plaintiffs, ARMANDO VALDES, JR. and VIOLETTA VALDES, individually, have incurred the expense of their son's hospitalization, medical and nursing care and treatment and have suffered the loss of their son's companionship, society, love, affection, and solace as well as loss of ordinary day-to-day services he would have rendered. Plaintiffs will suffer these losses in the future.

COUNT VIII—STRICT LIABILITY OF JOFA

Plaintiffs repeat and adopt Paragraphs 1 through 17 above and further allege:

63. Defendant, JOFA's, helmet which is at issue in this case, was designed, manufactured, assembled, tested, packaged, marketed, distributed and

sold by Defendant, JOFA, in a defective condition unreasonably dangerous to roller hockey users, such as the Plaintiff, in that:

a. it was inadequately ventilated for use in outdoor roller hockey in hot climates;

b. it was improperly colored for use in outdoor roller hockey in hot climates;

c. it did not contain adequate warnings concerning its use in hot climates; and

d. it did not contain adequate instructions concerning its use in hot climates.

64. Due to the defects described in Paragraph 63, the helmet designed, manufactured, assembled, tested, packaged, marketed, distributed and sold by Defendant, JOFA, was not reasonably fit for the purposes for which it was intended or for the purposes reasonably foreseeable at the time of its design, manufacture, assembly, testing, packaging, marketing, distribution and sale.

65. Due to the defects described in Paragraph 63, the JOFA brand helmet sold to Plaintiff by Defendant, JOFA was not reasonably fit for the purposes for which it was intended at the time of marketing, distribution and sale.

66. Due to the defects described in Paragraph 63, the JOFA brand helmet sold to Plaintiff was placed on the market in a defective or inherently dangerous condition.

67. Due to the defects described in Paragraph 63, the JOFA brand helmet sold to Plaintiff was unreasonably dangerous because the risk of danger to users, such as Plaintiff, ARMANDO VALDES, III, outweighed the benefits of the product.

68. Due to the defects described in Paragraph 63, the JOFA brand helmet sold to Plaintiff was dangerous beyond the expectation of the ordinary user when used as intended or in a manner reasonably foreseeable to the Defendant, JOFA.

69. Plaintiffs were unaware of the defective and unreasonably dangerous condition of the JOFA brand helmet at issue in this case.

70. Defendant, JOFA, knew or should have known that its helmet would be used without inspection for defects, and by placing it on the market Defendant, JOFA, represented that it would safely do the job for which it was intended.

71. As a direct and proximate result of the defects described above, Plaintiff, ARMANDO VALDES, III, incapacitated, suffered heat stroke resulting in bodily injury, including brain damage, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, loss of capacity for the enjoyment of life, the expense of hospitalization, medical and nursing care and treatment, and loss of wage earning capacity. The injuries are permanent in nature and Plaintiff will suffer these losses in the future.

72. As a further direct and proximate result, Plaintiffs, ARMANDO VALDES, JR. and VIOLETTA VALDES, individually, have incurred the expense of their son's hospitalization, medical and nursing

care and treatment and have suffered the loss of their son's companionship, society, love, affection, and solace as well as loss of ordinary day-to-day services he would have rendered. Plaintiffs will suffer these losses in the future.

COUNT IX—NEGLIGENCE OF JOFA

Plaintiffs repeat and adopt Paragraphs 1 through 17 and further allege:

73. At all times material, Defendant, JOFA, had a duty to design, manufacture, assemble, test, package, market, distribute and sell hockey helmets in a reasonably safe manner and to provide warnings to be utilized and relied on by users in a manner that would make said gear, and in particular the gear at issue in this case, reasonably safe for use.

74. At all times material, Defendant, JOFA, breached said duties owing to the Plaintiffs by failing to exercise reasonable care in the design, manufacture, assembly, testing, packaging, marketing, distribution and sale of the hockey helmet at issue in this case for the reasons set forth in Paragraph 63 above.

75. At all times material, Defendant, JOFA, knew, or in the exercise of reasonable care, should have known, that its acts and omissions with respect to the design, manufacturing, assembly, testing, packaging, marketing, distribution and sale of the hockey helmet at issue in this case, together with its lack of warnings and instruc-

tions, would result in injury to users such as Plaintiff, ARMANDO VALDES, III.

76. As a direct and proximate result of the above-described negligence, Plaintiff, ARMANDO VALDES, III, incapacitated, suffered heat stroke resulting in bodily injury, including brain damage, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, loss of capacity for the enjoyment of life, the expense of hospitalization, medical and nursing care and treatment, and loss of wage earning capacity. The injuries are permanent in nature and Plaintiff will suffer these losses in the future.

77. As a further direct and proximate result, Plaintiffs, ARMANDO VALDES, JR. and VIOLETTA VALDES, individually, have incurred the expense of their son's hospitalization, medical and nursing care and treatment and have suffered the loss of their son's companionship, society, love, affection, and solace as well as loss of ordinary day-to-day services he would have rendered. Plaintiffs will suffer these losses in the future.

COUNT X—STRICT LIABILITY OF KHF SPORTS

Plaintiffs repeat and adopt Paragraphs 1 through 17 above and further allege:

78. Defendant, KHF SPORTS, KOHO brand gloves which are at issue in this case, were designed, manufactured, assembled, tested, packaged, marketed, distributed and sold by Defendant, KHF SPORTS, in a defective condition

unreasonably dangerous to roller hockey users, such as the Plaintiff, in that:

a. they were inadequately ventilated for use in outdoor roller hockey in hot climates;

b. they were improperly colored for use in outdoor roller hockey in hot climates;

c. they did not contain adequate warnings concerning their use in hot climates; and

d. they did not contain adequate instructions concerning their use in hot climates;

79. Due to the defects described in Paragraph 78, the gloves designed, manufactured, assembled, tested, packaged, marketed, distributed and sold by Defendant, KHF SPORTS, were not reasonably fit for the purposes for which they were intended or for the purposes reasonably foreseeable at the time of their design, manufacture, assembly, testing, packaging, marketing, distribution and sale.

80. Due to the defects described in Paragraph 78, the KOHO brand gloves sold to Plaintiff by Defendant, KHF SPORTS, were not reasonably fit for the purposes for which they were intended at the time of marketing, distribution and sale by Defendant, KHF SPORTS.

81. Due to the defects described in Paragraph 78, KOHO brand gloves sold to Plaintiff by Defendant, KHF SPORTS, were placed on the market in a defective or inherently dangerous condition.

82. Due to the defects described in Paragraph 78, the KOHO brand gloves sold to Plaintiff were unreasonably dangerous because the risk of danger to users, such as Plaintiff, ARMANDO VALDES, III, outweighed the benefits of the product.

83. Due to the defects described in Paragraph 78, the KOHO brand gloves sold to Plaintiff were dangerous beyond the expectation of the ordinary user when used as intended or in a manner reasonably foreseeable to the Defendant, KHF SPORTS.

84. Plaintiffs were unaware of the defective and unreasonably dangerous condition of the KOHO brand gloves at issue in this case.

85. Defendant, KHF SPORTS, knew or should have known that its hockey gloves would be used without inspection for defects, and by placing them on the market, Defendant, KHF SPORTS, represented that they would safely do the job for which they were intended.

86. As a direct and proximate result of the defects described above, Plaintiff, ARMANDO VALDES, III, incapacitated, suffered heat stroke resulting in bodily injury, including brain damage, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, loss of capacity for the enjoyment of life, the expense of hospitalization, medical and nursing care and treatment, and loss of wage earning capacity. The injuries are permanent in nature and Plaintiff will suffer these losses in the future.

87. As a further direct and proximate result, Plaintiffs, ARMANDO VALDES, JR. and VIOLETTA

VALDES, individually, have incurred the expense of their son's hospitalization, medical and nursing care and treatment and have suffered the loss of their son's companionship, society, love, affection, and solace as well as loss of ordinary day-to-day services he would have rendered. Plaintiffs will suffer these losses in the future.

COUNT XI—NEGLIGENCE OF KHF SPORTS

Plaintiffs repeat and adopt Paragraphs 1 through 17 and further allege:

88. At all times material, Defendant, KHF SPORTS, had a duty to design, manufacture, assemble, test, package, market, distribute and sell hockey gloves in a reasonably safe manner and to provide warnings to be utilized and relied on by users in a manner that would make said gear, and in particular the gear at issue in this case, reasonably safe for use.

89. At all times material, Defendant, KHF SPORTS, breached said duties owing to the Plaintiffs by failing to exercise reasonable care in the design, manufacturing, assembly, testing, packaging, marketing, distribution and sale of the hockey gloves at issue in this case for the reasons set forth in Paragraph 78 above.

90. At all times material, Defendant, KHF SPORTS, knew, or in the exercise of reasonable care, should have known, that its acts and omissions with respect to the design, manufacturing, assembly, testing, packaging, marketing, distribution and sale of the hockey gloves at issue in this case, together with their lack of warnings and

instructions, would result in injury to users such as Plaintiff, ARMANDO VALDES, III.

91. As a direct and proximate result of the above-described negligence, Plaintiff, ARMANDO VALDES, III, incapacitated, suffered heat stroke resulting in bodily injury, including brain damage, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, loss of capacity for the enjoyment of life, the expense of hospitalization, medical and nursing care and treatment, and loss of wage earning capacity. The injuries are permanent in nature and Plaintiff will suffer these losses in the future.

92. As a further direct and proximate result, Plaintiffs, ARMANDO VALDES, JR. and VIOLETTA VALDES, individually, have incurred the expense of their son's hospitalization, medical and nursing care and treatment and have suffered the loss of their son's companionship, society, love, affection, and solace as well as loss of ordinary day-to-day services he would have rendered. Plaintiffs will suffer these losses in the future.

COUNT XII—STRICT LIABILITY OF THE HOCKEY COMPANY

Plaintiffs repeat and adopt Paragraphs 1 through 17 above and further allege:

93. Defendant, THE HOCKEY COMPANY's, helmet and gloves which are at issue in this case, were designed, manufactured, assembled, tested, packaged, marketed, distributed and sold by Defendant, THE HOCKEY COMPANY, in a defective

condition unreasonably dangerous to roller hockey users, such as the Plaintiff, in that:

a. they were inadequately ventilated for use in outdoor roller hockey in hot climates;

b. they were improperly colored for use in outdoor roller hockey in hot climates;

c. they did not contain adequate warnings concerning their use in hot climates; and

d. they did not contain adequate instructions concerning their use in hot weather conditions.

94. Due to the defects described in Paragraph 93, the helmet and gloves designed, manufactured, assembled, tested, packaged, marketed, distributed and sold by Defendant, THE HOCKEY COMPANY, were not reasonably fit for the purposes for which they were intended or for the purposes reasonably foreseeable at the time of their design, manufacture, assembly, testing, packaging, distribution and sale.

95. Due to the defects described in Paragraph 93, the JOFA brand helmet and KOHO brand gloves sold to Plaintiff by Defendant, THE HOCKEY COMPANY, were not reasonably fit for the purposes for which they were intended at the time of their design, manufacturing, assembly, testing, packaging, marketing, distribution and sale.

96. Due to the defects described in Paragraph 93, the JOFA brand helmet and KOHO brand

gloves sold to Plaintiff by Defendant, THE HOCKEY COMPANY, were placed on the market in a defective or inherently dangerous condition.

97. Due to the defects described in Paragraph 93, the JOFA brand helmet and KOHO brand gloves sold to Plaintiff by Defendant, THE HOCKEY COMPANY, were unreasonably dangerous because the risk of danger to users, such as Plaintiff, ARMANDO VALDES, III, outweighed the benefits of the products.

98. Due to the defects described in Paragraph 93, the JOFA brand helmet and KOHO brand gloves sold to Plaintiff by Defendant, THE HOCKEY COMPANY, were dangerous beyond the expectation of the ordinary user when used as intended or in a manner reasonably foreseeable to the Defendant, THE HOCKEY COMPANY.

99. Plaintiffs were unaware of the defective and unreasonably dangerous condition of the JOFA brand helmet and KOHO brand gloves at issue in this case.

100. Defendant, THE HOCKEY COMPANY, knew or should have known that its hockey gear would be used without inspection for defects, and by placing it on the market represented that it would safely do the job for which it was intended.

101. As a direct and proximate result of the defects described above, Plaintiff, ARMANDO VALDES, III, incapacitated, suffered heat stroke resulting in bodily injury, including brain damage, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, loss of capacity for the enjoyment of life,

the expense of hospitalization, medical and nursing care and treatment, and loss of wage earning capacity. The injuries are permanent in nature and Plaintiff will suffer these losses in the future.

102. As a further direct and proximate result, Plaintiffs, ARMANDO VALDES, JR. and VIOLETTA VALDES, individually, have incurred the expense of their son's hospitalization, medical and nursing care and treatment and have suffered the loss of their son's companionship, society, love, affection, and solace as well as loss of ordinary day-to-day services he would have rendered. Plaintiffs will suffer these losses in the future.

COUNT XIII—NEGLIGENCE OF THE HOCKEY COMPANY

Plaintiffs repeat and adopt Paragraphs 1 through 17 and further allege:

103. At all times material, Defendant, THE HOCKEY COMPANY, had a duty to design, manufacture, assemble, test, package, market, distribute and sell hockey gear in a reasonably safe manner and to provide warnings to be utilized and relied on by users in a manner that would make said gear, and in particular the gear at issue in this case, reasonably safe for use.

104. At all times material, Defendant, THE HOCKEY COMPANY, breached said duties owing to the Plaintiffs by failing to exercise reasonable care in the design, manufacturing, assembly, testing, packaging, marketing, distribution and sale of the hockey gear at issue in this case for the reasons set forth in Paragraph 93 above.

105. At all times material, Defendant, THE HOCKEY COMPANY, knew, or in the exercise of reasonable care, should have known, that its acts and omissions with respect to the design, manufacturing, assembly, testing, marketing, distribution and sale of the hockey equipment at issue in this case, together with its lack of warnings and instructions, would result in injury to users such as Plaintiff, ARMANDO VALDES, III.

106. As a direct and proximate result of the above-described negligence, Plaintiff, ARMANDO VALDES, III, incapacitated, suffered heat stroke resulting in bodily injury, including brain damage, pain and suffering, disability, physical impairment, disfigurement, mental anguish, inconvenience, loss of capacity for the enjoyment of life, the expense of hospitalization, medical and nursing care and treatment, and loss of wage earning capacity. The injuries are permanent in nature and Plaintiff will suffer these losses in the future.

107. As a further direct and proximate result, Plaintiffs, ARMANDO VALDES, JR. and VIOLETTA VALDES, individually, have incurred the expense of their son's hospitalization, medical and nursing care and treatment and have suffered the loss of their son's companionship, society, love, affection, and solace as well as loss of ordinary day-to-day services he would have rendered. Plaintiffs will suffer these losses in the future.

Wherefore, Plaintiffs, ARMANDO VALDES, III, incapacitated, by and through his legal guardians, ARMANDO VALDES, JR. and VIOLETTA VALDES, and ARMANDO VALDES, JR. and VIOLETTA VALDES, individually, sue Defendants, OPTIMIST

CLUB OF SUNILAND, INC., OPTIMIST INTERNATIONAL, MCNEIL-P.P.C., INC., THE SPORTS AUTHORITY, INC., JOFA AB, KHF SPORTS OY, and THE HOCKEY COMPANY, for compensatory damages and demand trial by jury.

LAW OFFICES OF SHARON L. BLAKE
9200 S. Dadeland Blvd., Ste. 311
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/s/ Donna B. Michelson
Donna B. Michelson, Esq.
Florida Bar No.: 305677

Article. V. – Amendment

The Congress, whenever two thirds of both Houses shall deem it necessary, shall propose Amendments to this Constitution, or, on the Application of the Legislatures of two thirds of the several States, shall call a Convention for proposing Amendments, which, in either Case, shall be valid to all Intents and Purposes, as part of this Constitution, when ratified by the Legislatures of three fourths of the several States, or by Conventions in three fourths thereof, as the one or the other Mode of Ratification may be proposed by the Congress; Provided that no Amendment which may be made prior to the Year One thousand eight hundred and eight shall in any Manner affect the first and fourth Clauses in the Ninth Section of the first Article; and that no State, without its Consent, shall be deprived of its equal Suffrage in the Senate.

Article. VI. – Debts, Supremacy, Oaths

All Debts contracted and Engagements entered into, before the Adoption of this Constitution, shall be as valid against the United States under this Constitution, as under the Confederation.

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

The Senators and Representatives before mentioned, and the Members of the several State Leg-

islatures, and all executive and judicial Officers, both of the United States and of the several States, shall be bound by Oath or Affirmation, to support this Constitution; but no religious Test shall ever be required as a Qualification to any Office or public Trust under the United States.

Article. VII. – Ratification

The Ratification of the Conventions of nine States, shall be sufficient for the Establishment of this Constitution between the States so ratifying the Same.

Done in Convention by the Unanimous Consent of the States present the Seventeenth Day of September in the Year of our Lord one thousand seven hundred and Eighty seven and of the Independence of the United States of America the Twelfth. In Witness whereof We have hereunto subscribed our Names.

21 C.F.R. § 341.80

§ 341.80 Labeling of nasal decongestant drug products.

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as a "nasal decongestant."

(b) Indications. The labeling of the product states, under the heading "Indications," the phrase listed in paragraph (b)(1) of this section, as appropriate, and may contain any additional phrases listed in paragraph (b)(2) of this section. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in paragraphs (b)(1) and (b)(2) of this section, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) (Select one of the following: "For the temporary relief of nasal congestion" or "Temporarily relieves nasal congestion") (which may be followed by any of the following in paragraphs (b)(1) (i), (ii), and (iii) of this section):

(i) "due to" (select one of the following: "the common cold" or "a cold").

(ii) "due to" (select one of the following: "hay fever," "hay fever (allergic rhinitis)," "hay fever or other upper respiratory allergies," or "hay fever or other upper respiratory allergies (allergic rhinitis)").

(2) In addition to the information identified in paragraph (b)(1) of this section, the labeling of the product may contain any (one or more) of the following statements:

(i) (Select one of the following: "For the temporary relief of" or "Temporarily relieves") (select one of the following: "stuffy nose," "stopped up nose," "nasal stuffiness," or "clogged up nose.")

(ii) (Select one of the following: "Reduces swelling of," "Decongests," or "Helps clear") "nasal passages; shrinks swollen membranes."

(iii) "Temporarily restores freer breathing through the nose."

(iv) "Helps decongest sinus openings and passages; temporarily relieves sinus congestion and pressure."

(v) "Promotes nasal and/or sinus drainage; temporarily relieves sinus congestion and pressure."

(c) Warnings. The labeling of the product contains the following warnings under the heading "Warnings":

(1) Oral nasal decongestants—

(i) For products containing phenylephrine hydrochloride, pseudoephedrine hydrochlo-

ride, pseudoephedrine sulfate, or phenylephrine bitartrate identified in § 341.20 (a)(1) through (a)(4) when labeled for adults.

(A) "Do not exceed recommended dosage. [first sentence in boldface type] If nervousness, dizziness, or sleeplessness occur, discontinue use and consult a doctor."

(B) "If symptoms do not improve within 7 days or are accompanied by fever, consult a doctor."

(C) "Do not take this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor."

(D) Drug interaction precaution. "Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product."

(ii) For products containing phenylephrine hydrochloride, pseudoephedrine hydrochloride, pseudoephedrine sulfate, or phenylephrine bitartrate identified in § 341.20 (a)(1) through (a)(4) when labeled for children under 12 years of age.

(A) "Do not exceed recommended dosage. [first sentence in boldface type] If nervousness, dizziness, or sleeplessness occur, discontinue use and consult a doctor."

(B) "If symptoms do not improve within 7 days or are accompanied by fever, consult a doctor."

(C) "Do not give this product to a child who has heart disease, high blood pressure, thyroid disease, or diabetes unless directed by a doctor."

(D) Drug interaction precaution. "Do not use in a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product."

(iii) For oral nasal decongestant products labeled for both adults and children under 12 years of age. The labeling of the product contains the warnings identified in paragraph (c)(1)(i) of this section.

(2) Topical nasal decongestants—

(i) For products containing any topical nasal decongestant identified in § 341.20(b) when labeled for adults.

(A) "Do not exceed recommended dosage." [sentence in boldface type]

(B) "This product may cause temporary discomfort such as burning, stinging, sneezing, or an increase in nasal discharge."

(C) "The use of this container by more than one person may spread infection."

(ii) For products containing levmetamfetamine identified in § 341.20(b)(1) when used in an inhalant dosage form and when labeled for adults. "Do not use this product for more than 7 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, ask a doctor."

(iii) For products containing ephedrine, ephedrine hydrochloride, ephedrine sulfate, naphazoline hydrochloride, oxymetazoline hydrochloride, phenylephrine hydrochloride, or xylometazoline hydrochloride identified in § 341.20(b)(2), (b)(3), (b)(4), (b)(6), (b)(7), (b)(8), and (b)(10) when used as nasal sprays, drops, or jellies and when labeled for adults.

(A) "Do not use this product for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, consult a doctor."

(B) "Do not use this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor."

(iv) For products containing naphazoline hydrochloride identified in § 341.20(b)(6) at a concentration of 0.05 percent. "Do not use this product in children under 12 years of age because it may cause sedation if swallowed."

(v) For products containing propylhexedrine identified in § 341.20(b)(9) when used in an inhalant dosage form and when labeled for adults. "Do not use this product for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, consult a doctor."

(vi) For products containing any topical nasal decongestant identified in § 341.20(b) when labeled for children under 12 years of age. The labeling of the product contains the warnings identified in paragraph (c)(2)(i) of this section.

(vii) For products containing levmetamfetamine identified in § 341.20(b)(1) when used in an inhalant dosage form and when labeled for children under 12 years of age. "Do not use this product for more than 7 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, ask a doctor."

(viii) For products containing ephedrine, ephedrine hydrochloride, ephedrine sulfate, naphazoline hydrochloride, oxymetazoline hydrochloride, phenylephrine hydrochloride, or xylometazoline hydrochloride identified in § 341.20(b)(2), (b)(3), (b)(4), (b)(6), (b)(7), (b)(8), and (b)(10) when used as nasal sprays,

drops, or jellies and when labeled for children under 12 years of age.

(A) "Do not use this product for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, consult a doctor."

(B) "Do not use this product in a child who has heart disease, high blood pressure, thyroid disease, or diabetes unless directed by a doctor."

(ix) For products containing propylhexedrine identified in § 341.20(b)(9) when used in an inhalant dosage form and when labeled for children under 12 years of age. "Do not use this product for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, consult a doctor."

(x) For topical nasal decongestant products labeled for both adults and for children under 12 years of age. The labeling of the product contains the applicable warnings identified in paragraphs (c)(2)(i), (c)(2)(ii), (c)(2)(iii), and (c)(2)(v) of this section.

(d) Directions. The labeling of the product contains the following information under the heading "Directions":

(1) Oral nasal decongestants—

(i) For products containing phenylephrine hydrochloride identified in § 341.20(a)(1). Adults and children 12 years of age and over:

10 milligrams every 4 hours not to exceed 60 milligrams in 24 hours. Children 6 to under 12 years of age: 5 milligrams every 4 hours not to exceed 30 milligrams in 24 hours. Children 2 to under 6 years of age: 2.5 milligrams every 4 hours not to exceed 15 milligrams in 24 hours. Children under 2 years of age: consult a doctor.

(ii) For products containing pseudoephedrine hydrochloride or pseudoephedrine sulfate identified in § 341.20 (a)(2) and (a)(3). Adults and children 12 years of age and over: 60 milligrams every 4 to 6 hours not to exceed 240 milligrams in 24 hours. Children 6 to under 12 years of age: 30 milligrams every 4 to 6 hours not to exceed 120 milligrams in 24 hours. Children 2 to under 6 years of age: 15 milligrams every 4 to 6 hours not to exceed 60 milligrams in 24 hours. Children under 2 years of age: consult a doctor.

(iii) For products containing phenylephrine bitartrate identified in § 341.20(a)(4). Include information on the number of dosage units and the quantity of water the dosage units are to be dissolved in prior to administration as shown in the following table:

Age[1]	Dose[1]
Adults and children 12 years of age and over	15 6 milligrams every 4 hours not to exceed 62 4 milligrams in 24 hours
Children 6 to 12 under of age	7.8 milligrams every 4 hours not to exceed 31 2 milligrams in 24 hours
Children under 6 years of age	Ask a doctor

[1] Headings are not required to appear in the product's labeling

(2) Topical nasal decongestants—

(i) For products containing levmetamfetamine identified in § 341.20(b)(1) when used in an inhalant dosage form. The product delivers in each 800 milliliters of air 0.04 to 0.150 milligrams of levmetamfetamine. Adults: 2 inhalations in each nostril not more often than every 2 hours. Children 6 to under 12 years of age (with adult supervision): 1 inhalation in each nostril not more often than every 2 hours. Children under 6 years of age: ask a doctor.

(ii) For products containing ephedrine, ephedrine hydrochloride, or ephedrine sulfate identified in § 341.20(b)(2), (3), and (4)—

(A) Nasal drops or sprays—For a 0.5-percent aqueous solution. Adults and children 12 years of age and over: 2 or 3 drops or sprays in each nostril not more often than every 4 hours. Children 6 to under 12 years of age (with adult supervision): 1 or 2 drops or sprays in each nostril not more often than every 4 hours. Children under 6 years of age: consult a doctor.

(B) Nasal jelly—For a 0.5-percent water-based jelly. Adults and children 6 to under 12 years of age (with adult supervision): place a small amount in each nostril and inhale well back into the nasal passages. Use not more often than every 4 hours.

(iii) For products containing naphazoline hydrochloride identified in § 341.20(b)(6)—

(A) Nasal drops or sprays—

(1) For a 0.05-percent aqueous solution. Adults and children 12 years of age and over: 1 or 2 drops or sprays in each nostril not more often than every 6 hours. Do not give to children under 12 years of age unless directed by a doctor.

(2) For a 0.025-percent aqueous solution. Children 6 to under 12 years of age (with adult supervision): 1 or 2 drops or sprays in each nostril not more often than every 6 hours. Children under 6 years of age: consult a doctor.

(B) Nasal jelly—

(1) For a 0.05-percent water-based jelly. Adults and children 12 years of age and over: place a small amount in each nostril and inhale well back into the nasal passages. Use not more often than every 6 hours. Do not give to children under 12 years of age unless directed by a doctor.

(2) For a 0.025-percent water-based jelly. Children 6 to under 12 years of age (with adult supervision): place a small amount in each nostril and inhale well back into the nasal passages. Use not more often than every 6 hours. Children under 6 years of age: consult a doctor.

(iv) For products containing oxymetazoline hydrochloride identified in § 341.20(b)(7)—

(A) Nasal drops or sprays—

(1) For a 0.05-percent aqueous solution. Adults and children 6 to under 12 years of age (with adult supervision): 2 or 3 drops or sprays in each nostril not more often than every 10 to 12 hours. Do not exceed 2 doses in any 24-hour period. Children under 6 years of age: consult a doctor.

(2) A 0.025-percent aqueous solution in a container having either a calibrated dropper or a metered-dose spray that delivers no more than 0.027 milligrams of oxymetazoline per three drops or three sprays. Children 2 to under 6 years of age (with adult supervision): 2 or 3 drops or sprays in each nostril not more often than every 10 to 12 hours. Use only recommended amount. Do not exceed 2 doses in any 24-hour period. [previous two sentences in boldface type] Children under 2 years of age: consult a doctor.

(B) Nasal jelly—For a 0.05-percent water-based jelly. Adults and children 6 to under 12 years of age (with adult supervision): place a small amount in each nostril and inhale well back into the nasal passages. Use not more often than every 10 to 12 hours. Do not exceed 2 doses in any 24-hour period. Children under 6 years of age: consult a doctor.

(v) For products containing phenylephrine hydrochloride identified in § 341.20(b)(8)—

(A) Nasal drops or sprays—

(1) For a 1-percent aqueous solution. Adults and children 12 years of age and over: 2 or 3 drops or sprays in each nostril not more often than every 4 hours. Do not give to children under 12 years of age unless directed by a doctor.

(2) For a 0.5-percent aqueous solution. Adults and children 12 years of age and over: 2 or 3 drops or sprays in each nostril not more often than every 4 hours. Do not give to children under 12 years of age unless directed by a doctor.

(3) For a 0.25-percent aqueous solution. Adults and children 6 to under 12 years of age (with adult supervision): 2 or 3 drops or sprays in each nostril not more often than every 4 hours. Children under 6 years of age: consult a doctor.

(4) A 0.125-percent aqueous solution in a container having either a calibrated dropper or a metered-dose spray that delivers no more than 0.135 milligrams of phenylephrine per three drops or three sprays. Children 2 to under 6 years of age (with adult supervision): 2 or 3 drops or sprays in each nostril not more often than every 4 hours. Use only recommended amount. [previous sentence in boldface type] Children under 2 years of age: consult a doctor.

(B) Nasal jelly—

(1) For a 1-percent water-based jelly. Adults and children 12 years of age and over: place a small amount in each nostril and inhale well back into the nasal passages. Use not more often than every 4 hours. Do not give to children under 12 years of age unless directed by a doctor.

(2) For a 0.5-percent water-based jelly. Adults and children 12 years of age and over: place a small amount in each nostril and inhale well back into the nasal passages. Use not more often than every 4 hours. Do not give to children under 12 years of age unless directed by a doctor.

(3) For a 0.25-percent water-based jelly. Adults and children 6 to under 12 years of age (with adult supervision): place a small amount in each nostril and inhale well back into the nasal passages. Use not more often than every 4 hours. Children under 6 years of age: consult a doctor.

(vi) For products containing propylhexedrine identified in § 341.20(b)(9) when used in an inhalant dosage form. The product delivers in each 800 milliliters of air 0.40 to 0.50 milligrams of propylhexedrine. Adults and children 6 to under 12 years of age (with adult supervision): 2 inhalations in each nostril not more often than every 2 hours. Children under 6 years of age: consult a doctor.

(vii) For products containing xylometazoline hydrochloride identified in § 341.20(b)(10)—

(A) Nasal drops or sprays—

(1) For a 0.1-percent aqueous solution. Adults and children 12 years of age and over: 2 or 3 drops or sprays in each nostril not more often than every 8 to 10 hours. Do not give to children under 12 years of age unless directed by a doctor.

(2) A 0.05-percent aqueous solution in a container having either a calibrated dropper or a metered-dose spray that delivers no more than 0.054 milligrams of xylometazoline per three drops or three sprays. Children 6 to under 12 years of age (with adult supervision): 2 or 3 drops or sprays in each nostril not more often than every 8 to 10 hours. Children 2 to under 6 years of age (with adult supervision): 2 or 3 drops or sprays in each nostril not more often than every 8 to 10 hours. Use only recommended amount. Do not exceed 3 doses in any 24-hour period. [previous two sentences in boldface type] Children under 2 years of age: consult a doctor.

(B) Nasal jelly—

(1) For a 0.1-percent water-based jelly. Adults and children 12 years of age and over: place a small amount in each nostril and inhale well back into the nasal passages. Use not more often than every 8 to 10 hours. Do not give to

children under 12 years of age unless directed by a doctor.

(2) For a 0.05-percent water-based jelly. Children 6 to under 12 years of age (with adult supervision): place a small amount in each nostril and inhale well back into the nasal passages. Use not more often than every 8 to 10 hours. Children under 6 years of age: consult a doctor.

(viii) Other required statements--For products containing levmetamfetamine or propylhexedrine identified in § 341.20(b)(1) or (b)(9) when used in an inhalant dosage form.

(A) "This inhaler is effective for a minimum of 3 months after first use."

(B) "Keep inhaler tightly closed."

[59 FR 43409, Aug. 23, 1994; 63 FR 40650, July 30, 1998; 64 FR 13295, March 17, 1999; 64 FR 18571, April 15, 1999; 65 FR 8, Jan. 3, 2000; 65 FR 38191, June 20, 2000; 70 FR 58977, Oct. 11, 2005; 71 FR 43362, Aug. 1, 2006]

SOURCE: 51 FR 35339, Oct. 2, 1986; 52 FR 30055, Aug. 12, 1987; 54 FR 39636, Sept. 27, 1989; 62 FR 51516, Oct. 1, 1997, unless otherwise noted.

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

21 C. F. R. § 341.80, 21 CFR § 341.80

Current through October 14, 2010; 75 FR 63377

21 C.F.R. § 330.10

§ 330.10 Procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded, and for establishing monographs.

For purposes of classifying over-the-counter (OTC) drugs as drugs generally recognized among qualified experts as safe and effective for use and as not misbranded drugs, the following regulations shall apply:

(a) Procedure for establishing OTC drug monographs—

(1) Advisory review panels. The Commissioner shall appoint advisory review panels of qualified experts to evaluate the safety and effectiveness of OTC drugs, to review OTC drug labeling, and to advise him on the promulgation of monographs establishing conditions under which OTC drugs are generally recognized as safe and effective and not misbranded. A single advisory review panel shall be established for each designated category of OTC drugs and every OTC drug category will be considered by a panel. The members of a panel shall be qualified experts (appointed by the Commissioner) and may include persons from lists submitted by organizations representing professional, consumer, and industry interests. The Commissioner shall designate the chairman of each panel. Summary minutes of all meetings shall be made.

(2) Request for data and views. The Commissioner will publish a notice in the Federal Register requesting interested persons to submit, for

review and evaluation by an advisory review panel, published and unpublished data and information pertinent to a designated category of OTC drugs. Data and information submitted pursuant to a published notice, and falling within the confidentiality provisions of 18 U.S.C. 1905, 5 U.S.C. 552(b), or 21 U.S.C. 331(j), shall be handled by the advisory review panel and the Food and Drug Administration as confidential until publication of a proposed monograph and the full report(s) of the panel or until the Commissioner places the panel's recommendations on public display at the office of the Division of Dockets Management. Thirty days thereafter such data and information shall be made publicly available and may be viewed at the office of the Division of Dockets Management of the Food and Drug Administration, except to the extent that the person submitting it demonstrates that it still falls within the confidentiality provisions of one or more of those statutes. To be considered, eight copies of the data and/or views on any marketed drug within the class must be submitted, preferably bound, indexed, and on standard sized paper (approximately 8 1/2 x 11 inches). When requested, abbreviated submissions should be sent. All submissions must be in the following format:

OTC Drug Review Information

I. Label(s) and all labeling (preferably mounted and filed with the other data—facsimile labeling is acceptable in lieu of actual container labeling).

II. A statement setting forth the quantities of active ingredients of the drug.

III. Animal safety data.

A. Individual active components.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

B. Combinations of the individual active components.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

C. Finished drug product.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

IV. Human safety data.

A. Individual active components.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

3. Documented case reports. Identify expected or frequently reported side effects.

4. Pertinent marketing experiences that may influence a determination as to the safety of each individual active component.

5. Pertinent medical and scientific literature.

B. Combinations of the individual active components.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

3. Documented case reports. Identify expected or frequently reported side effects.

4. Pertinent marketing experiences that may influence a determination as to the safety of combinations of the individual active components.

5. Pertinent medical and scientific literature.

C. Finished drug product.-

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

3. Documented case reports. Identify expected or frequently reported side effects.

4. Pertinent marketing experiences that may influence a determination as to the safety of the finished drug product.

5. Pertinent medical and scientific literature.

V. Efficacy data.

A. Individual active components.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

3. Documented case reports. Identify expected or frequently reported side effects.

4. Pertinent marketing experiences that may influence a determination on the efficacy of each individual active component.

5. Pertinent medical and scientific literature.

B. Combinations of the individual active components.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

3. Documented case reports. Identify expected or frequently reported side effects.

4. Pertinent marketing experiences that may influence a determination on the efficacy of combinations of the individual active components.

5. Pertinent medical and scientific literature.

C. Finished drug product.

1. Controlled studies.

2. Partially controlled or uncontrolled studies.

3. Documented case reports. Identify expected or frequently reported side effects.

4. Pertinent marketing experiences that may influence a determination on the efficacy of the finished drug product.

5. Pertinent medical and scientific literature.

VI. A summary of the data and views setting forth the medical rationale and purpose (or lack thereof) for the drug and its ingredients and the scientific basis (or lack thereof) for the conclusion that the drug and its ingredients have been proven safe and effective for the intended use. If there is an absence of controlled studies in the material submitted, an explanation as to why such studies are not considered necessary must be included.

VII. An official United States Pharmacopeia (USP)-National Formulary (NF) drug monograph for the active ingredient(s) or botanical drug sub-

stance(s), or a proposed standard for inclusion in an article to be recognized in an official USP-NF drug monograph for the active ingredient(s) or botanical drug substance(s). Include information showing that the official or proposed compendial monograph for the active ingredient or botanical drug substance is consistent with the active ingredient or botanical drug substance used in the studies establishing safety and effectiveness and with the active ingredient or botanical drug substance marketed in the OTC product(s) to a material extent and for a material time. If differences exist, explain why.

(3) Deliberations of an advisory review panel. An advisory review panel will meet as often and for as long as is appropriate to review the data submitted to it and to prepare a report containing its conclusions and recommendations to the Commissioner with respect to the safety and effectiveness of the drugs in a designated category of OTC drugs. A panel may consult any individual or group. Any interested person may request an opportunity to present oral views to the panel; such request may be granted or denied by the panel. Such requests for oral presentations should be in written form including a summarization of the data to be presented to the panel. Any interested person may present written data and views which shall be considered by the panel. This information shall be presented to the panel in the format set forth in paragraph (a)(2) of this section and within the time period established for the drug category in the notice for review by a panel.

(4) Standards for safety, effectiveness, and labeling. The advisory review panel, in reviewing the data submitted to it and preparing its conclusions and recommendations, and the Commissioner, in reviewing the conclusions and recommendations of the panel and the published proposed, tentative, and the final monographs, shall apply the following standards to determine general recognition that a category of OTC drugs is safe and effective and not misbranded:

(i) Safety means a low incidence of adverse reactions or significant side effects under adequate directions for use and warnings against unsafe use as well as low potential for harm which may result from abuse under conditions of widespread availability. Proof of safety shall consist of adequate tests by methods reasonably applicable to show the drug is safe under the prescribed, recommended, or suggested conditions of use. This proof shall include results of significant human experience during marketing. General recognition of safety shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data.

(ii) Effectiveness means a reasonable expectation that, in a significant proportion of the target population, the pharmacological effect of the drug, when used under adequate directions for use and warnings against unsafe use, will provide clinically significant relief of the type claimed. Proof of effectiveness shall consist of controlled clinical investigations as defined in § 314.126(b) of this chapter, unless this requirement is waived on the basis of a showing that it

is not reasonably applicable to the drug or essential to the validity of the investigation and that an alternative method of investigation is adequate to substantiate effectiveness. Investigations may be corroborated by partially controlled or uncontrolled studies, documented clinical studies by qualified experts, and reports of significant human experience during marketing. Isolated case reports, random experience, and reports lacking the details which permit scientific evaluation will not be considered. General recognition of effectiveness shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data.

(iii) The benefit-to-risk ratio of a drug shall be considered in determining safety and effectiveness.

(iv) An OTC drug may combine two or more safe and effective active ingredients and may be generally recognized as safe and effective when each active ingredient makes a contribution to the claimed effect(s); when combining of the active ingredients does not decrease the safety or effectiveness of any of the individual active ingredients; and when the combination, when used under adequate directions for use and warnings against unsafe use, provides rational concurrent therapy for a significant proportion of the target population.

(v) Labeling shall be clear and truthful in all respects and may not be false or misleading in any particular. It shall state the intended uses and results of the product; adequate directions for proper use; and warnings against unsafe use,

side effects, and adverse reactions in such terms as to render them likely to be read and understood by the ordinary individual, including individuals of low comprehension, under customary conditions of purchase and use.

(vi) A drug shall be permitted for OTC sale and use by the laity unless, because of its toxicity or other potential for harmful effect or because of the method or collateral measures necessary to its use, it may safely be sold and used only under the supervision of a practitioner licensed by law to administer such drugs.

(5) Advisory review panel report to the Commissioner. An advisory review panel may submit to the Commissioner a report containing its conclusions and recommendations with respect to the conditions under which OTC drugs falling within the category covered by the panel are generally recognized as safe and effective and not misbranded. Included within this report shall be:

(i) A recommended monograph or monographs covering the category of OTC drugs and establishing conditions under which the drugs involved are generally recognized as safe and effective and not misbranded (Category I). This monograph may include any conditions relating to active ingredients, labeling indications, warnings and adequate directions for use, prescription or OTC status, and any other conditions necessary and appropriate for the safety and effectiveness of drugs covered by the monograph.

(ii) A statement of active ingredients, labeling claims or other statements, or other conditions

reviewed and excluded from the monograph on the basis of the panel's determination that they would result in the drug's not being generally recognized as safe and effective or would result in misbranding (Category II).

(iii) A statement of active ingredients, labeling claims or other statements, or other conditions reviewed and excluded from the monograph on the basis of the panel's determination that the available data are insufficient to classify such condition under either paragraph (a)(5)(i) or (ii) of this section and for which further testing is therefore required (Category III). The report may recommend the type of further testing required and the time period within which it might reasonably be concluded.

(6) Proposed monograph. After reviewing the conclusions and recommendations of the advisory review panel, the Commissioner shall publish in the Federal Register a proposed order containing:

(i) A monograph or monographs establishing conditions under which a category of OTC drugs or a specific or specific OTC drugs are generally recognized as safe and effective and not misbranded (Category I).

(ii) A statement of the conditions excluded from the monograph on the basis of the Commissioner's determination that they would result in the drug's not being generally recognized as safe and effective or would result in misbranding (Category II).

(iii) A statement of the conditions excluded from the monograph on the basis of the Commissioner's determination that the available data are insufficient to classify such conditions under either paragraph (a)(6)(i) or (ii) of this section (Category III).

(iv) The full report(s) of the panel to the Commissioner.[1]

The proposed order shall specify a reasonable period of time within which conditions falling within paragraph (a)(6)(iii) of this section may be continued in marketed products while the data necessary to support them are being obtained for evaluation by the Food and Drug Administration. The summary minutes of the panel meetings shall be made available to interested persons upon request. Any interested person may, within 90 days after publication of the proposed order in the Federal Register, file with the Division of Dockets Management of the Food and Drug Administration written comments in triplicate. Comments may be accompanied by a memorandum or brief in support thereof. All comments may be reviewed at the office of the Division of Dockets Management between the hours of 9 a.m. and 4 p.m., Monday through Friday. Within 30 days after the final day for submission of comments, reply comments may be filed with the Division of Dockets Management; these comments shall be utilized to reply to comments made by other interested persons and not to reiterate a position. The Commissioner may

[1] The official CFR appears to have inadvertently omitted the last two sentences of this paragraph added by 67 FR 3073.

satisfy this requirement by publishing in the Federal Register a proposed order summarizing the full report of the advisory review panel, containing its conclusions and recommendations, to obtain full public comment before undertaking his own evaluation and decision on the matters involved. Alternatively, the Commissioner may satisfy this requirement by placing the panel's recommendations and the data it considered on public display at the office of the Division of Dockets Management and publishing a notice of their availability in the Federal Register. This notice of availability may be included as part of the tentative order in accord with paragraph (a)(7) of this section.

(7) Tentative final monograph.

(i) After reviewing all comments, reply comments, and any new data and information or, alternatively, after reviewing a panel's recommendations, the Commissioner shall publish in the Federal Register a tentative order containing a monograph establishing conditions under which a category of OTC drugs or specific OTC drugs are generally recognized as safe and effective and not misbranded. Within 90 days, any interested person may file with the Division of Dockets Management, Food and Drug Administration, written comments or written objections specifying with particularity the omissions or additions requested. These objections are to be supported by a brief statement of the grounds therefor. A request for an oral hearing may accompany such objections.

(ii) The Commissioner may also publish in the Federal Register a separate tentative order containing a statement of those active ingredients reviewed and proposed to be excluded from the monograph on the basis of the Commissioner's determination that they would result in a drug product not being generally recognized as safe and effective or would result in misbranding. This order may be published when no substantive comments in opposition to the panel report or new data and information were received by the Food and Drug Administration under paragraph (a)(6)(iv) of this section or when the Commissioner has evaluated and concurs with a panel's recommendation that a condition be excluded from the monograph. Within 90 days, any interested person may file with the Division of Dockets Management, Food and Drug Administration, written objections specifying with particularity the provision of the tentative order to which objection is made. These objections are to be supported by a brief statement of the grounds therefor. A request for an oral hearing may accompany such objections.

(iii) Within 12 months after publishing a tentative order pursuant to paragraph (a)(7)(i) of this section, any interested person may file with the Division of Dockets Management, Food and Drug Administration, new data and information to support a condition excluded from the monograph in the tentative order.

(iv) Within 60 days after the final day for submission of new data and information, comments on the new data and information may be filed

with the Division of Dockets Management, Food and Drug Administration.

(v) New data and information submitted after the time specified in this paragraph but prior to the establishment of a final monograph will be considered as a petition to amend the monograph and will be considered by the Commissioner only after a final monograph has been published in the Federal Register unless the Commissioner finds that good cause has been shown that warrants earlier consideration.

(8) Oral hearing before the Commissioner. After reviewing objections filed in response to the tentative final monograph, the Commissioner, if he finds reasonable grounds in support thereof, shall by notice in the Federal Register schedule an oral hearing. The notice scheduling an oral hearing shall specify the length of the hearing and how the time shall be divided among the parties requesting the hearing. The hearing shall be conducted by the Commissioner and may not be delegated.

(9) Final monograph. After reviewing the objections, the entire administrative record including all new data and information and comments, and considering the arguments made at any oral hearing, the Commissioner shall publish in the Federal Register a final order containing a monograph establishing conditions under which a category of OTC drugs or a specific or specific OTC drugs are generally recognized as safe and effective and not misbranded. The monograph shall become effective as specified in the order.

(10) Administrative record.

(i) All data and information to be considered in any proceeding pursuant to this section shall be submitted in response to the request for data and views pursuant to paragraph (a)(2) of this section, in response to any other notice published in the Federal Register, or accepted by the panel during its deliberations pursuant to paragraph (a)(3) of this section or submitted to the Division of Dockets Management as part of the comments during the 90-day period and 30-day rebuttal comment period permitted pursuant to paragraph (a)(6) of this section or submitted to the Division of Dockets Management during the 12-month period or as part of the comments during the 60-day period permitted pursuant to paragraph (a)(7) of this section.

(ii) The Commissioner shall make all decisions and issue all orders pursuant to this section solely on the basis of the administrative record, and shall not consider data or information not included as part of the administrative record.

(iii) The administrative record shall consist solely of the following material: All notices and orders published in the Federal Register, all data and views submitted in response to the request published pursuant to paragraph (a)(2) of this section, in response to any other notice published in the Federal Register, or accepted by the panel during its deliberations pursuant to paragraph (a)(3) of this section, all minutes of panel meetings, the panel report(s), all comments and rebuttal comments submitted on the proposed monograph and all new data and information

submitted pursuant to paragraph (a)(6) of this section, all objections submitted on the tentative final monograph and all new data and information and comments submitted pursuant to paragraph (a)(7) of this section, the complete record of any oral public hearing conducted pursuant to paragraph (a)(8) of this section, all other comments requested at any time by the Commissioner, all data and information for which the Commissioner has reopened the administrative record, and all other material that the Commissioner includes in the administrative record as part of the basis for the Commissioner's decision.

(11) Court appeal. The monograph contained in the final order constitutes final agency action from which appeal lies to the courts. The Food and Drug Administration will request consolidation of all appeals in a single court. Upon court appeal, the Commissioner may, at his discretion, stay the effective date for part or all of the monograph pending appeal and final court adjudication.

(12) Amendment of monographs.

(i) The Commissioner may propose on the Commissioner's own initiative to amend or repeal any monograph established pursuant to this section. Any interested person may petition the Commissioner for such proposal pursuant to § 10.30 of this chapter. The Commissioner may deny the petition if the Commissioner finds a lack of safety or effectiveness employing the standards in paragraph (a)(4) of this section (in which case the appeal provisions of paragraph (a)(11) of this section shall apply), or the Com-

missioner may publish a proposed amendment or repeal in the Federal Register if the Commissioner finds general recognition of safety and effectiveness employing the standards in paragraph (a)(4) of this section. Any interested person may, within 90 days after publication of the proposed order in the Federal Register, file with the Division of Dockets Management, Food and Drug Administration, written comments in triplicate. Comments may be accompanied by a memorandum or brief in support thereof. All comments may be reviewed in the Division of Dockets Management between the hours of 9 a.m. and 4 p.m., Monday through Friday. After reviewing the comments, the Commissioner shall publish a final order amending the monograph established under the provisions of paragraph (a)(9) of this section or withdraw the proposal if comments opposing the amendment are persuasive. A new drug application may be submitted in lieu of, or in addition to, a petition under this paragraph.

(ii) A new drug application may be submitted in lieu of a petition to amend the OTC drug monograph only if the drug product with the condition that is the subject of the new drug application has not been marketed on an interim basis (such as under the provisions of paragraph (a)(6)(iii) of this section), all clinical testing has been conducted pursuant to a new drug application plan, and no marketing of the product with the condition for which approval is sought is undertaken prior to approval of the new drug application. The Food and Drug Administration

shall handle a new drug application as a petition for amendment of a monograph, and shall review it on that basis, if the provisions of this paragraph preclude approval of a new drug application but permit the granting of such a petition.

(b) Regulatory action. Any product which fails to conform to an applicable monograph after its effective date is liable to regulatory action.

(c) Information and data submitted under this section shall include, with respect to each nonclinical laboratory study contained in the application, either a statement that the study was conducted in compliance with the good laboratory practice regulations set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(d) [Reserved]

(e) Institutional review and informed consent. Information and data submitted under this section after July 27, 1981, shall include statements regarding each clinical investigation involving human subjects, from which the information and data are derived, that it either was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter, or was not subject to such requirements in accordance with §§ 56.104 or 56.105, and that it was conducted in compliance with the requirements for informed consent set forth in part 50 of this chapter.

(f) Financial certification or disclosure statement. Any clinical data submitted under this section must be accompanied by financial certifications or disclo-

sure statements or both as required by part 54 of this chapter.

[39 FR 11741, March 29, 1974, as amended at 39 FR 39556, Nov. 8, 1974; 42 FR 19141, April 12, 1977; 42 FR 54800, Oct. 11, 1977; 43 FR 60022, Dec. 20, 1978; 46 FR 8460, 8955, Jan. 27, 1981; 46 FR 14340, Feb. 27, 1981; 46 FR 21360, April 10, 1981; 46 FR 47738, Sept. 29, 1981; 50 FR 7516, Feb. 22, 1985; 51 FR 16265, May 1, 1986; 55 FR 11581, March 29, 1990; 63 FR 5253, Feb. 2, 1998; 67 FR 3073, Jan. 23, 2002]

SOURCE: 39 FR 11741, March 29, 1974; 51 FR 16265, May 1, 1986; 54 FR 39636, Sept. 27, 1989; 62 FR 51516, Oct. 1, 1997, unless otherwise noted.

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

21 C. F. R. § 330.10, 21 CFR § 330.10

Current through October 14, 2010; 75 FR 63377

21 C.F.R. § 330.1

§ 330.1 General conditions for general recognition as safe, effective and not misbranded.

An over-the-counter (OTC) drug listed in this subchapter is generally recognized as safe and effective and is not misbranded if it meets each of the conditions contained in this part and each of the conditions contained in any applicable monograph. Any product which fails to conform to each of the conditions contained in this part and in an applicable monograph is liable to regulatory action.

(a) The product is manufactured in compliance with current good manufacturing practices, as established by Parts 210 and 211 of this chapter.

(b) The establishment(s) in which the drug product is manufactured is registered, and the drug product is listed, in compliance with Part 207 of this chapter. It is requested but not required that the number assigned to the product pursuant to Part 207 of this chapter appear on all drug labels and in all drug labeling. If this number is used, it shall be placed in the manner set forth in Part 207 of this chapter.

(c)(1) The product is labeled in compliance with chapter V of the Federal Food, Drug, and Cosmetic Act (the act) and subchapter C et seq. of this chapter, including the format and content requirements in § 201.66 of this chapter. An OTC drug product that is not in compliance with chapter V and subchapter C, including § 201.66 of this chapter, is subject to regulatory action. For purposes of § 201.61(b) of this chapter, the statement of identity of the product shall

be the term or phrase used in the applicable OTC drug monograph established in this part.

(2) The "Uses" section of the label and labeling of the product shall contain the labeling describing the "Indications" that have been established in an applicable OTC drug monograph or alternative truthful and nonmisleading statements describing only those indications for use that have been established in an applicable monograph, subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act. Any other labeling under this subchapter and subchapter C et seq. of this chapter shall be stated in the exact language where exact language has been established and identified by quotation marks in an applicable OTC drug monograph or by regulation (e.g., § 201.63 of this chapter), except as provided in paragraphs (i) and (j) of this section.

(d) The advertising for the product prescribes, recommends, or suggests its use only under the conditions stated in the labeling.

(e) The product contains only suitable inactive ingredients which are safe in the amounts administered and do not interfere with the effectiveness of the preparation or with suitable tests or assays to determine if the product meets its professed standards of identity, strength, quality, and purity. Color additives may be used only in accordance with section 721 of the act and Subchapter A of this chapter.

(f) The product container and container components meet the requirements of § 211.94 of this chapter.

(g) The labeling for all drugs contains the general warning: "Keep out of reach of children." [highlighted in bold type]. The labeling of drugs shall also state as follows: For drugs used by oral administration, "In case of overdose, get medical help or contact a Poison Control Center right away"; for drugs used topically, rectally, or vaginally and not intended for oral ingestion, "If swallowed, get medical help or contact a Poison Control Center right away"; and for drugs used topically and intended for oral use, "If more than used for" (insert intended use, e.g., pain) "is accidentally swallowed, get medical help or contact a Poison Control Center right away." The Food and Drug Administration will grant an exemption from these general warnings where appropriate upon petition, which shall be maintained in a permanent file for public review by the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

(h) Where no maximum daily dosage limit for an active ingredient is established in this part, it is used in a product at a level that does not exceed the amount reasonably required to achieve its intended effect.

(i) The following terms may be used interchangeably in the labeling of OTC drug products, provided such use does not alter the meaning of the labeling that has been established and identified in an applicable monograph or by regulation. The following terms shall not be used to change in any way the

title, headings, and subheadings required under § 201.66(c)(1) through (c)(9) of this chapter:

(1) "Abdominal" or "stomach" (in context only).

(2) "Administer" or "give".

(3) "Aggravate(s)" or "make(s) worse".

(4) "Application of this product" or "applying".

(5) "Are uncertain" or "do not know".

(6) "Ask" or "consult" or "contact".

(7) "Asking" or "consulting".

(8) "Assistance" or "help" or "aid".

(9) "Associated with" or "due to" or "caused by".

(10) "Avoid contact with eyes" or "do not get into eyes".

(11) "Avoid inhaling" or "do not inhale".

(12) "Before a doctor is consulted" or "without first consulting your doctor" or "consult your doctor before".

(13) "Beverages" or "drinks".

(14) "Clean" or "cleanse".

(15) "Consulting" or "advising".

(16) "Continue(s)" or "persist(s)" or "is persistent" or "do(es) not go away" or "last(s)".

(17) "Daily" or "every day".

(18) "Develop(s)" or "begin(s)" or "occur(s)".

(19) "Difficulty" or "trouble".

(20) "Difficulty in urination" or "trouble urinating".

(21) "Discard" or "throw away".

(22) "Discontinue" or "stop" or "quit".

(23) "Doctor" or "physician".

(24) "Drowsiness" or "the drowsiness effect".

(25) "Drowsiness may occur" or "you may get drowsy".

(26) "Enlargement of the" or "an enlarged".

(27) "Especially in children" or especially children".

(28) "Exceed" or "use more than" or "go beyond".

(29) "Exceed recommended dosage" or "use more than directed".

(30) "Excessive" or "too much".

(31) "Excitability may occur" or "you may get excited".

(32) "Experience" or "feel".

(33) "For relief of" or "relieves".

(34) "For temporary reduction of" or "temporarily reduces".

(35) "For the temporary relief of" or "temporarily relieves".

(36) "For the treatment of" or "treats".

(37) "Frequently" or "often".

(38) "Give to" or "use in".

(39) "Immediately" or "right away" or "directly".

(40) "Immediately" or "as soon as".

(41) "Immediately following" or "right after".

(42) "Improve(s)" or "get(s) better" or "make(s) better".

(43) "Increased" or "more".

(44) "Increase your risk of" or "cause".

(45) "Indication(s)" or "Use(s)".

(46) "Inhalation" or "puff".

(47) "In persons who" or "if you" or "if the child".

(48) "Instill" or "put".

(49) "Is (are) accompanied by" or "you also have" (in context only) or "(optional: that) occur(s) with".

(50) "Longer" or "more".

(51) "Lung" or "pulmonary".

(52) "Medication(s)" or "medicine(s)" or "drug(s)".

(53) "Nervousness, dizziness, or sleeplessness occurs" or "you get nervous, dizzy, or sleepless".

(54) "Not to exceed" or "do not exceed" or "not more than".

(55) "Obtain(s)" or "get(s)".

(56) "Passages" or "passageways" or "tubes".

(57) "Perforation of" or "hole in".

(58) "Persistent" or "that does not go away" or "that continues" or "that lasts".

(59) "Per day" or "daily".

(60) "Presently" or "now".

(61) "Produce(s)" or "cause(s)".

(62) "Prompt(ly)" or "quick(ly)" or "right away".

(63) "Reduce" or "minimize".

(64) "Referred to as" or "of".

(65) "Sensation" or "feeling".

(66) "Solution" or "liquid".

(67) "Specifically" or "definitely".

(68) "Take" or "use" or "give".

(69) "Tend(s) to recur" or "reoccur(s)" or "return(s)" or "come(s) back".

(70) "To avoid contamination" or "avoid contamination" or "do not contaminate".

(71) "To help" or "helps".

(72) "Unless directed by a doctor" or "except under the advice of a doctor" or "unless told to do so by a doctor".

(73) "Use caution" or "be careful".

(74) "Usually" or "generally" (in context only).

(75) "You" ("Your") or "the child" ("the child's").

(76) "You also have" or "occurs with".

(77) "When practical" or "if possible".

(78) "Whether" or "if".

(79) "Worsen(s)" or "get(s) worse" or "make(s) worse".

(j) The following connecting terms may be deleted from the labeling of OTC drug products, provided such deletion does not alter the meaning of the labeling that has been established and identified in an applicable monograph or by regulation. The following terms shall not be used to change in any way the specific title, headings, and subheadings required under § 201.66(c)(1) through (c)(9) of this chapter:

(1) "And".

(2) "As may occur with".

(3) "Associated" or "to be associated".

(4) "Consult a doctor".

(5) "Discontinue use".

(6) "Drug Interaction Precaution".

(7) "Due to".

(8) "Except under the advice and supervision of a physician".

(9) "If this occurs".

(10) "In case of".

(11) "Notice".

(12) "Or".

(13) "Occurring with".

(14) "Or as directed by a doctor".

(15) "Such as".

(16) "Such as occurs with".

(17) "Tends to".

(18) "This product".

(19) "Unless directed by a doctor".

(20) "While taking this product" or "before taking this product".

(21) "Within".

[39 FR 11741, March 29, 1974, as amended at 40 FR 11718, March 13, 1975; 40 FR 13496, March 27, 1975; 42 FR 15674, March 22, 1977; 46 FR 8459, Jan. 27, 1981; 50 FR 8996, March 6, 1985; 51 FR 16265, May 1, 1986; 55 FR 11581, March 29, 1990; 59 FR 4000, Jan. 28, 1994; 59 FR 14365, March 28, 1994; 64 FR 13294, March 17, 1999; 64 FR 18571, April 15, 1999; 65 FR 38191, June 20, 2000]

SOURCE: 39 FR 11741, March 29, 1974; 51 FR 16265, May 1, 1986; 54 FR 39636, Sept. 27, 1989; 62 FR 51516, Oct. 1, 1997, unless otherwise noted.

AUTHOIRTY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

21 C. F. R. § 330.1, 21 CFR § 330.1

Current through November 11, 2010; 75 FR 69326

21 U.S.C.A. § 379r

§ 379r. National uniformity for nonprescription drugs

(a) In general

Except as provided in subsection (b), (c)(1), (d), (e), or (f) of this section, no State or political subdivision of a State may establish or continue in effect any requirement—

(1) that relates to the regulation of a drug that is not subject to the requirements of section 353(b)(1) or 353(f)(1)(A) of this title; and

(2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this chapter, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

(b) Exemption

(1) In general

Upon application of a State or political subdivision thereof, the Secretary may by regulation, after notice and opportunity for written and oral presentation of views, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a State or political subdivision requirement that—

(A) protects an important public interest that would otherwise be unprotected, including the health and safety of children;

(B) would not cause any drug to be in violation of any applicable requirement or prohibition under Federal law; and

(C) would not unduly burden interstate commerce.

(2) Timely action

The Secretary shall make a decision on the exemption of a State or political subdivision requirement under paragraph (1) not later than 120 days after receiving the application of the State or political subdivision under paragraph (1).

(c) Scope

(1) In general

This section shall not apply to—

(A) any State or political subdivision requirement that relates to the practice of pharmacy; or

(B) any State or political subdivision requirement that a drug be dispensed only upon the prescription of a practitioner licensed by law to administer such drug.

(2) Safety or effectiveness

For purposes of subsection (a) of this section, a requirement that relates to the regulation of a drug shall be deemed to include any requirement relating to public information or any other form of public communication relating to a warning of any kind for a drug.

(d) Exceptions

(1) In general

In the case of a drug described in subsection (a)(1) of this section that is not the subject of an application approved under section 355 of this title or section 357 of this title (as in effect on the day before November 21, 1997) or a final regulation promulgated by the Secretary establishing conditions under which the drug is generally recognized as safe and effective and not misbranded, subsection (a) of this section shall apply only with respect to a requirement of a State or political subdivision of a State that relates to the same subject as, but is different from or in addition to, or that is otherwise not identical with—

(A) a regulation in effect with respect to the drug pursuant to a statute described in subsection (a)(2) of this section; or

(B) any other requirement in effect with respect to the drug pursuant to an amendment to such a statute made on or after November 21, 1997.

(2) State initiatives

This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997.

(e) No effect on product liability law

Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

(f) State enforcement authority

Nothing in this section shall prevent a State or political subdivision thereof from enforcing, under any relevant civil or other enforcement authority, a requirement that is identical to a requirement of this chapter.

CREDIT(S)

(June 25, 1938, c. 675, § 751, as added Nov. 21, 1997, Pub.L. 105-115, Title IV, § 412(a), 111 Stat. 2373.)

HISTORICAL AND STATUTORY NOTES

Revision Notes and Legislative Reports

1997 Acts. House Conference Report No. 105-399, see 1997 U.S. Code Cong. and Adm. News, p. 2881.

Effective and Applicability Provisions

1997 Acts. Amendments by Pub.L. 105-115, the Food and Drug Administration Modernization Act of 1997, effective 90 days after November **21**, 1997, except as otherwise provided, see section 501 of Pub.L. 105-115, set out as a note under **21** U.S.C.A. § 321.

21 U.S.C.A. § 379r, 21 USCA § 379r

Current through P.L. 111-264 (excluding P.L. 111-203, 111-257,and 111-259) approved 10-8-10

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CALENDAR NO. 105

105th Congress
1st Session

SENATE

Report 105-43

FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997

JULY 1, 1997—Ordered to be printed

Filed, under authority of the order of the Senate of June 27, 1997

Mr. JEFFORDS, from the Committee on Labor and Human Resources, submitted the following

REPORT

together with

ADDITIONAL AND MINORITY VIEWS

[To accompany S. 830]

The Committee on Labor and Human Resources, to which was referred the bill (S. 830) to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, and biological products, and for

other purposes, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends that the bill (as amended) do pass.

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h. A minor reanalysis of data previously submitted to the application (determined by the agency as fitting the class 1 category).

i. Other minor clarifying information (determined by the agency as fitting the class 1 category).

j. Other specific items may be added later as the Agency gains experience with the scheme and will be communicated via guidance documents to industry.

5. Class 2 resubmissions are resubmissions that include any other items, including any item that

would require presentation to an advisory committee.

6. A Type A meeting is a meeting which is necessary for an otherwise stalled drug development program to proceed (a "critical path meeting).

7. A Type B meeting is a (1) pre-IND, (2) end of Phase 1 (for Subpart E or Subpart H or similar products) or end of Phase 2/pre-Phase 3, or (3) a pre-NDA/PLA/BLA meeting. Each requestor should usually only request 1 each of these Type B meetings for each potential application (NDA/PLA/BLA) (or combination of closely related products, i.e., same active ingredient but different dosage forms being developed concurrently).

8. A Type C meeting is any other type of meeting.

TITLE VIII—MISCELLANEOUS

Clarification of seizure authority

There are two situations under which FDA-regulated products are imported into the United States and enter domestic commerce. The first occurs when the product passes FDA and Customs scrutiny at the border and is permitted entry into the country. The second is under section 801(d)(3), as added by the FDA Export Reform and Enhancement Act of 1996, which permits products to be imported into the United States solely for processing with the requirement that the finished product subsequently be exported. Section 803 amends the seizure provisions in section 304(d)(l) of the act to clarify that any person who seeks to

export an article that has been imported under either of these conditions, pursuant to the export provisions in section 801(e) of the Act, must demonstrate that the article was intended for export at the time that it entered commerce. The clarification of section 304(d) applies only to seized and condemned imported articles and does not affect articles proffered for import that are refused entry under section 801(a) and properly exported within 90 days of refusal.

National uniformity for nonprescription drugs and cosmetics

The economic strength and vitality for consumer products in the United States rests upon the tradition of one vast nationwide marketplace, regulated by strong Federal and State agencies committed to protecting the public health. An essential element of a nationwide marketplace is a national uniform system of regulation. It is intended that the FDA provide national leadership in assuring the safety, effectiveness, and proper labeling and packaging for nonprescription drugs and cosmetics marketed throughout the country, under the Federal Food, Drug, and Cosmetic Act, the Posion Prevention Packaging Act, and the Fair Packaging and Labeling Act.

Under our Federal system, it is important that State and local officials enforce the same regulatory requirements for products as do our Federal officials. Different or additional requirements as the State or local level can work against our national marketplace, confuse consumers, raise prices, undermine public confidence in our regulatory system and in products important to the

public health, and result in divergent public health protection throughout the country.

Federal law currently provides strong public health protection nonprescription drugs and cosmetics; and their constituents. Nonprescription drugs are subject to careful and comprehensive regulation by the FDA. The conditions under which nonprescription drugs are considered safe and effective, for use by the lay consumer, are specified by FDA in nonprescription drug monographs or by new drug and antibiotic drug applications. FDA also ensures that the labeling of nonprescription drugs provides adequate directions for use, and adequate warnings against unsafe use, through these monographs and drug marketing applications, as well as through a number of general and specific labeling regulations. The FDA also has strong legal authority to regulate cosmetics. A cosmetic is considered adulterated if it contains a substance that may be injurious to users. The FDA has required that every cosmetic ingredient and every finished cosmetic product be substantiated for safety before it can be marketed. A cosmetic is misbranded if the safety of the product or an ingredient has not been established prior to marketing and that fact is not disclosed in a label warning. FDA also requires all ingredients to be declared on the label of cosmetics. For both nonprescription drugs and cosmetics, the FDA has clear statutory authority to require warnings or to ban unsafe ingredients. Use of any unsafe ingredient, or any false or misleading labeling, for a nonprescription drug or a cosmetic is unlawful and subject to regulatory action. The

FDA authority in this area extends from manufacture through retail sale of these products.

Section 808 of the legislation therefore established a new section 761 of the Federal Food, Drug, and Cosmetic Act that adopts, as a general rule, the requirement of national uniformity in the regulation of nonprescription drugs and cosmetics and their constituents. No State or local government is permitted to impose different or additional requirements that relate to the subject matter covered by the three Federal laws as they apply to nonprescription drugs and cosmetics. These include requirements imposed on product manufacture or composition, labeling, advertising, or any other form of public notification or communication.

Under the legislation, all States may vigorously enforce requirements for nonprescription drugs and cosmetics that are identical to the Federal requirements, including the Federal prohibition against the adulteration or misbranding of these products. Most States have enacted laws regulating nonprescription drugs and cosmetics laws. These identical State requirements may be enforced by State officials, without first notifying the FDA or obtaining any Federal approval, using compliance powers that are different from or in addition to the Federal compliance mechanisms, e.g., the power of a State to order an embargo or recall of a violative product or to impose civil penalties. States may also continue to use such traditional revenue measures as registration fees. Accordingly, one consistent national regulatory system will be implemented, relying upon both Federal and State enforcement, providing

strengthened public health protection throughout the country.

There may occasionally be situations where a local problem could justify a different or additional regulatory requirement for non-prescription drugs or cosmetics in a particular State. The legislation therefore specifically authorizes States to petition for an exemption from the general rule of national uniformity under these circumstances. The FDA may grant an exemption if the State demonstrates that its proposed local requirement protects an important public interest that is not protected under the Federal laws, the local requirement would not cause any nonprescription drug or cosmetic to be in violation of any Federal law, and the local requirement would not unduly burden interstate commerce. State exemption petitions should be given a high priority by the FDA; and should be handled promptly upon receipt. Where the problem identified by a State could represent a national problem, on the other hand, the proper way for a State to proceed would be by petitioning the FDA to change the national requirements, using established agency procedures.

The legislation allows State officials to place a nonprescription drug on prescription only, to solve a local problem such as a localized outbreak of abuse of a product. Once the problem has abated, the drug can then be switched back to nonprescription status. Similarly, State laws will continue to apply to the practice of pharmacy, i.e., to the licensing, discipline, and professional duties of pharmacists. Accordingly, the legislation clearly

recognizes and reflects the paramount need to protect the public health, both locally and nationally.

A State, locality, or person may continue to take advantage of their right to petition the FDA, where it has not issued a regulation, to make a certain requirement a national requirement, under the right supplied to them in 21 CFR 10.30, the citizen petition provision of the Code of Federal Regulations.

The FDA jurisdiction relating to dissemination of information about nonprescription drugs and cosmetics and their constituents applies to the label and labeling for these products. It is important that any State or local requirements imposed on industry relating to the advertising of nonprescription drugs or cosmetics, or to any other form of public notification or communication relating to these products and their constituents, be identical with the FDA requirements for the label and labeling of these products. Accordingly, the legislation extends national uniformity to the requirements for all forms of public information and public communication, not just to the label and labeling. The legislation, however, would not preclude State officials from issuing their own State warnings in accordance with local law. Similarly, voluntary programs such as the "Mr. Yuk" initiative sponsored by local Poison Control Centers will not be affected.

Under the legislation, national uniformity is provided for all of the types of requirements for nonprescription drugs and cosmetics and their constituents under State laws that are related to requirements included in the Federal laws, e.g., requirements to prevent adulteration or mis-

branding or other illegal marketing or to issue public notice about the safety of constituents. All forms of State requirements that affect these products are included within the general rule of national uniformity, whether they are specifically denominated as applying to nonprescription drugs and cosmetics or more broadly apply to unfair competition or to all chemicals, ingredients, or contaminants to which consumers and other members of the public are exposed. To the extent that any type of State law imposes a requirement for a warning or other type of public notification with respect to nonprescription drugs or cosmetics or any constituent, that requirement is prohibited unless such a requirement is prescribed under one of the three identified Federal laws and the State requirement is identical to the Federal requirement.

Finally, the legislation explicitly provides that it shall not be construed to modify or otherwise affect the traditional product liability law of any State. Tort liability rules and requirements would remain unchanged and unaffected.

The committee further notes the importance of nonprescription drugs in the nation's health care system. While consumers spend less than 2 cents of their health care dollar on nonprescription drugs, such drugs produce substantial savings to the individual and the health care system in reductions in physician visits, prescription drug costs, insurance costs, lost time from work, and travel. The committee notes that products switched from prescription to nonprescription status contribute significantly to these savings. For example, according to a study conducted by

Kline & Company, consumer health care savings attributable to self-care with nonprescription medicines reached $20.6 billion in 1996. Kline calculated that medicines transferred from prescription to non-prescription status were responsible for $12.9 billion of the $20.6 billion savings. The savings are determined by calculating what consumers would be likely to spend if, instead of using nonprescription medicines, they were to see a doctor, purchase a prescription medicine and lose time from work.

The committee therefore expects that the FDA, as part of its mission set forth in section 101 of this legislation (i.e., "shall promptly and efficiently review clinical research and take appropriate action on the marketing of regulated products in a manner that does not unduly impede innovation or product availability") will establish appropriate procedures and policies, Including performance standards, to expedite the review of applications to switch prescription drugs to nonprescription status. The committee encourages the FDA to give strong consideration to establishing a separate offer for nonprescription drugs and conferring on that office primary review and sign-off authority for applications to switch drugs from prescription to nonprescription status. At a minimum, the committee recommends that an individual or individuals within the Center for Drug Evaluation and Research be designated to ensure timely and efficient agency review and action on such applications and that the agency consider using the explicit authority granted to it to contract for outside expert review when such con-

tracts would achieve more timely and efficient reviews."

Information program on clinical trials for serious or life-threatening diseases

Sec. 808 amends section 402 of the Public Health Services Act to establish a registry of clinical trials, both publicly or privately funded, of experimental drugs and biologicals for serious or lifethreatening medical conditions. Registry information must he understandable to the general public and include the purpose of the experimental protocol, trial eligibility criteria, and sites and contact points for people wishing to enroll in a trial. Patients, health care providers, researchers and the public would access the registry through toll-free telephone communications and other information systems. Sec. 808 also requires the Secretary of HHS, within *2* years after enactment, to investigate and report on whether it is necessary or feasible to include medical device trials in the registry. The purpose of the registry is to simplify the process through which individuals with serious or life-threatening medical conditions obtain information about opportunities to participate in clinical trials of experimental therapies.

Pharmacy compounding

Section 809 of S. 830 is intended to clarify the application of the Federal Food, Drug and Cosmetic Act to the professional practice of pharmacist compounding of drug products. States currently have the authority to license pharmacists and regulate pharmacies, including the scope

of pharmacy practice. All States include compounding as a core component of the profession of pharmacy. While the Food, Drug and Cosmetic Act specifically exempts pharmacies from inspection and registration provisions of the Act, it has been the contention of the Food and Drug Administration that compounded products are not exempt from the Act's new drug provisions. The committee has found that clarification is necessary to address current concerns and uncertainty about the Food and Drug Administration's regulatory authority over pharmacy compounding.

The committee has worked extensively with the Food and Drug Administration and other interested parties to reach consensus on how to ensure continued availability of compounded drug products as a component of individualized therapy, while limiting the scope of compounding so as to prevent small-scale manufacturing under the guise of compounding. Section 809 establishes parameters under which compounding is appropriate and lawful. This section is not intended to subvert the requirements that apply to investigational new drugs or to result in experimentation without appropriate human subject protections, including proper informed consent.

The views of the Committee with respect to certain subsections of Section 809 are outlined below:

> The exemptions in section (h)(1) are limited to compounding for an individual patient based on the medical need of such patient for the particular drug compounded. To qualify for the exemptions, the pharmacist or physician must be able to cite a legitimate medical need for the compounded product that would

explain why a commercially available drug product would not be appropriate. Although recording the medical need directly on each prescription order would not be required, this technique would be one of many acceptable ways of documenting the medical need for each compounded drug product. This medical need would not include compounding drugs that are essentially copies of commercially available drug products for largely economic reasons. The pharmacist may rely on appropriately documented input from the physician as to whether a commercially available drug product is not appropriate for the identified individual patient.

Implementation of subsection (h)(1)(B)(I)(I)(bb), regarding bulk drug substances, is expected to coincide with the implementation of subsection (h)(3), except that compliance with the standards of an applicable United States Pharmacopeia monograph is not dependent on any further implementation under subsection (h)(3).

Among other requirements, a bulk drug substance used for compounding must have been manufactured in an establishment that has registered under section 510 of the Act. In addition to applying to domestic manufacturing establishments, this requirement shall also apply to foreign establishments, once the requirement in section 801 of this Act, which requires foreign establishments to register and list under section 510 of the Act, becomes effective.

In compliance with subsection (h)(1)(B)(I)(III), pharmacists may retain each certificate of analysis until the supply of such bulk drug substance has been exhausted, and must record in the compounding record the manufacturer, repackager (if any), and the lot number of the bulk drug substance.

The list published pursuant to subsection (h)(1)(B)(iv) includes drug products that have been withdrawn or removed from the market because the finished drug product and/or a component thereof has been found to be unsafe or not effective. The Federal Register document that includes the list should briefly describe the basis for the withdrawal or removal and provide & interested parties with an opportunity to comment. The list should not include products that have been withdrawn or removed solely because of manufacturing issues.

Interested parties should be allowed to petition, under 21 CFR §10.30, to change the listing of a particular drug product under subsection (h)(l)(B)(v) should research and technology yield advances which correct the compounding difficulties.

Regarding subsection (h)(2)(B), until the State agency of jurisdiction in which the pharmacy is located enters into a memorandum of understanding (MOU) with the Secretary or 180 days after the development of the standard MOU, whichever comes first, the exemption shall not apply if inordinate quantities of compounded products are distributed outside

of the State in which the compounding pharmacy or physician is located. "Inordinate" quantities means amounts typically associated with ordinary commercial drug manufacturing.

As required under subsection (h)(3), the Secretary will be required to promulgate regulations limiting compounding to drug substances that are components of drug products approved by the Secretary and to other drug substances as the Secretary may identify. It is expected that the Secretary's regulations would allow compounding with drug products, or the components of drug products, that are lawfully distributed, including drug products that are not new drugs under 21 U.S.C. §321(p) and drug substances that authorized for use under an effective Investigational New Drug application (IND) protocol under 21 U.S.C. §355(I) and 21 CFR Part 312. The FDA may, in development of the list for other substances approved for compounding, consult with pharmacy organizations and other interested parties, beyond the United States Pharmacopeia.

V. Cost Estimate

U.S. Congress,
Congressional Budget Office,
Washington, DC. June 27, 1997

Hon. James M. Jeffords,

Chairman, Committee on Labor and Human Resources, United States Senate, Washington, DC.

Dear Mr. Chairman: The Congressional Budget Office has prepared the enclosed cost estimate for S. 830, the Food and Drug Administration Modernization and Accountability Act of 1997.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Anne Hunt.

Sincerely,

June E. O'Neill, *Director*

S. 830—Food and Drug Administration Modernization and Accountability Act of 1997

Summary: S. 830 would reauthorize the Prescription Drug User Fee Act (PDUFA) of 1992, which empowers the Food and Drug Administration (FDA) to collect user fees from the pharmaceutical industry. The user fee program would be reauthorized, with some modifications, for an additional five years. The bill would also amend the Food, Drug and Cosmetic Act (FD&CA) and the Public Health Service Act to reform the FDA's regulatory and approval processes for drugs biological products, devices, foods and animal drugs. One provision would a six-month extension of market exclusivity fur pharmaceutical manufac-

turers who conduct pediatric studies on select prescription drugs.

CBO estimates that enacting S. 830 would result in net additional discretionary spending of $63 million in 1993 and $445 million over the 1993-2002 period, assuming appropriation of the authorized amounts. Reauthorizing the user fee program would yield $601 million in offsetting collections over five years; these amounts would also be authorized to be spent, subject to appropriation. Extending market exclusivity for certain drugs would increase direct spending by $65 million over the 1998-2002 period.

By preempting state and local laws that regulate nonprescription drugs differently than federal law, S. 830 would impose an intergovernmental mandate as defined in the Unfunded Mandates Reform Act (UMRA). CBO estimates that compliance with this mandate would result in no significant costs for state and local governments.

Estimated cost to the Federal Government: The estimated budgetary impact of S. 830 is shown in the following table. For the purposes of this estimate, CBO assumes that all amounts authorized in the bill would be appropriated by the start of each fiscal year and that outlays would follow the historical spending patterns for the FDA. The costs of this legislation fall within budget function 550 (Health).

[By fiscal year, in millions of dollars]

	1997	1998	1999	2000	2001	2002
SPENDING SUBJECT TO APPROPRIATION						
Spending Under Current Law						
Estimated Authorizations:						
Authorization Level	887	919	949	982	1,016	1,050
Estimated Outlays	895	914	937	971	1,005	1,038
Collection of User Fees:						
Authorization Level	-101	0	0	0	0	0
Estimated Outlays	-101	0	0	0	0	0
Sending of User Fees:						
Authorization Level	101	0	0	0	0	0
Estimated Outlays	100	26	5	0	0	0
Proposed Changes						
Estimated Authorizations:						
Authorization Level	0	63	93	102	90	97
Estimated Outlays	0	38	61	80	83	93
Collection of User Fees:						
Authorization Level	0	-110	-116	-119	-128	-128
Estimated Outlays	0	-110	-116	-119	-128	-128
Spending of User Fees						
Authorization Level	0	110	116	119	128	128
Estimated Outlays	0	104	114	118	126	128
SPENDING SUBJECT TO APPROPRIATION						
Spending Under S.830						
Estimated Authorizations:						
Authorization Level[1]	887	982	1,042	1,084	1,106	1,147
Estimated Outlays	895	952	998	1,051	1,088	1,131
Collection of User Fees.						
Authorization Level[1]	-101	-110	-116	-119	-128	-128
Estimated Outlays	-101	-110	-116	-119	-128	-128
Spending of User Fees						
Authorization Level[1]	101	110	116	119	128	128
Estimated Outlays	100	130	119	118	126	128
DIRECT SPENDING						
Direct Spending						
Estimated Budget Authority	0	0	7	18	28	11
Estimated Outlays	0	0	7	18	28	11

[1]The 1997 level is the amount appropriated for that year.

BASIS OF ESTIMATE

Estimated authorizations: In addition to reauthorizing the user fee program, the bill would reform the FDA's approval and regulatory processes with the intent of accelerating product approvals and alleviating regulatory requirements. It would require the FDA to comply with statutory deadlines for reviewing new products. S. 830 would require the FDA, in coordination with the National Institutes of Health (NIH) and the Centers for Disease Control (CDC), to establish a program to provide information on treatment, detection, and prevention of serious diseases and on clinical trials currently studying these conditions. Other provisions would result in small budgetary savings.

Enforced Deadlines for FDA Action on Submissions. The bill would require the Secretary to develop and publish in the Federal Register a plan bringing the FDA into compliance with the obligations and deadlines contained in the FD&CA and other relevant statutes. Among other objectives, the plan must bring the FDA into full compliance with the statutory review deadlines in the FD&CA by July 1, 1999. The plan must also ensure that the FDA eliminate any backlog of submissions by January 1, 2000. The agency would also be required to implement the FD&CA inspection and postmarket monitoring requirements by July 1, 1999.

Assuming that the volume and quality standards for reviews were to remain constant, the FDA would require additional staff and resources to reduce review times significantly and eliminate

the backlog of product submissions. Because S. 830 would somewhat relax current FDA regulations, the number of product applications could increase, placing further demands on the agency's resources. CBO estimates that the additional personnel and resources necessary to meet the proposed deadlines would exceed any savings realized through regulatory relief offered by S. 830. This provision would cost the federal government an estimated $50 million in 1998 and $267 million over five years.

Information Program on Clinical Trials. S. 830 would require the Director of the National Institutes of Health in coordination with the FDA and the Centers for Disease Control to establish a program to provide information on treatment, detection, and prevention of serious diseases and on clinical trials currently studying these conditions. This program would include establishing a database of all federally and privately funded clinical trials and a toll-free telephone information line available to health care providers, researchers, individuals with serious diseases, and all other members of the public.

The NIH already has such a program for clinical trials that it funds for cancer, AIDS, and rare diseases. Privately funded clinical trials are also included in these databases on a voluntary basis. The FDA would be able to disclose information on clinical trials, and NIH would be required to expand its current database significantly to accommodate the increase in volume of trials and information. After the system was set up, additional maintenance costs would be incurred to keep up with the status and results of clinical tri-

als, and with new protocols on treatment and prevention of serious diseases and conditions. Costs would also arise to operate a telephone information line staffed by health professionals.

CBO based its estimate on the cost of maintaining the current data banks and information networks, the estimated portion of clinical trials currently contained in NIH's databases, and conversations with professionals experienced in this area. CBO assumes that it would take two years to create a system that would meet the minimum requirements specified in the bill, at a cost of $20 million in 1998 and $45 million in 1999. For each year thereafter, CBO estimated a cost of $50 million for maintenance and quality improvement. Costs would total $215 million over the 1998-2002 period.

Third-Party Review of Applications. The FDA would be required to accredit independent entities and individuals to review and make initial classification recommendations on section 510(k) device submissions. Devices that are life-sustaining or supporting, intended for implantation for more than one year, or designated as class III devices under section 515 would be exempted from this provision, except at the agency's discretion. The FDA would also have the discretion to allow accredited entities and individuals review premarket approval (PMA) applications for class III devices. Compensation arrangements for these reviews would be made between the sponsor and the reviewer. CBO estimates that this proposal would save approximately $1 million over five years.

Reclassification of Class III Devices. S. 830 would amend the FDA's current practice of automatically designating as class III products new devices that are not substantially equivalent to a legally marketed predicate device. Sponsors of devices designated as class III could request the FDA to classify their device as a class I or II device, and could make a recommendation about the classification. The FDA would have 60 days to make a final determination on a sponsor's recommendation. This provision would reduce the number of premarket applications reviewed by the FDA, saving $1 million in 1998 and $12 million over five years.

Reporting Product Changes to the FDA. The bill would waive the requirement that manufacturers file an additional application for an investigational device exemption for minor changes in the intended use or design of an investigational device. Minor changes are those that would not affect the efficacy or safety of the device. CBO estimates that this provision would save approximately $11 million over five years.

User fees

The bill would reauthorize current prescription drug user fees through September 30, 2002. The current authorization expires at the end of fiscal year 1997. The bill would also authorize new fees to be levied on manufacturers and suppliers of food contact substances. Proceeds from these fees would be available for spending, subject to appropriation.

Reauthorization of the Prescription Drug User Fee Act of 1992. As with current law, the reau-

thorized program would levy three types of user fees on pharmaceutical manufacturers: application and supplement fees, establishment fees, and product fees. Aggregate amounts of such fees are specified in the bill for each of fiscal years 1998-2002; these amounts would be adjusted to reflect cumulative inflation since 1997. CBO's estimate assumes that the inflation adjustment would apply to the specified authorization, not to the prior year's actual authorization. Under the proposal, the FDA would make annual adjustments so that the total revenues collected for establishment and product fees would equal those for application and supplement fees. The amounts collected are authorized to be spent, subject to appropriation. CBO estimates that the FDA would collect $110 million in 1998 and $601 million over five years.

Any fees collected in excess of the amount specified in the appropriations act for a given year would be credited to the FDA appropriations account and subtracted from the amount of fees authorized for the following year. The FDA could not assess the user fees unless appropriations for FDA salaries and expenses, excluding any user fees, were at least equal to appropriations for 1997, adjusted for inflation.

Fees for Food Contact Substances. The bill would include food contact substances among the items regulated under the FD&CA. Food contact substance could be used only if the FDA issued, and the food contact substance met, standards for the use of such additives. Alternatively, manufacturers or suppliers could give the FDA advance notification that the intended use of their food

contact substance was safe according to agency regulations. Unless the FDA determined that the food contact substance was unsafe within 120 days of this notice, the notification would become effective.

The Secretary could authorize a fee, based on the resources needed to process these notifications, to be collected from individuals submitting notifications. The fee would be available to the FDA until expended, without fiscal year limitation. Although CBO cannot determine the amount of such fees, the provision would have no net budgetary impact, because the fees would be set to cover the agency's costs for reviewing and processing food contact substance notifications.

Direct spending

The bill would grant an additional six months of market exclusivity to pharmaceutical manufacturers that conduct pediatric studies on select drugs. This provision would affect direct spending because it would increase costs for the Medicaid rebate program and the Federal Employees Health Benefit Program (FEHBP). This provision would apply to pediatric studies commenced before January 1, 2004.

The Secretary of Health and Human Services, through the Commissioner of the FDA, would issue a list of drugs for which additional pediatric information might yield a health benefit.

If manufacturers of targeted drugs submitted pediatric studies to the FDA, their product would receive an additional six months of market exclusivity. This benefit would accrue to both approved drugs and those awaiting approval. Manufacturers

of an approved drug that received an extension under this provision could, if eligible, receive an additional six months of exclusivity for a supplemental application.

By extending the market exclusivity of certain drugs, this proposal would increase prescription drug costs for Medicaid, FEHBP, Veterans Affairs (VA) facilities, the Department of Defense, and the Public Health Service for the six months of the extension. In the absence of this provision, these programs may have had access to less expensive generic products. In the case of Medicaid and FEHBP, the additional costs of this provision would represent direct spending. At this time, the costs to FEHBP, the VA, the Department of Defense, and the Public Health Service cannot be determined. CBO estimates that this provision would have no net budgetary effect in 1998 but would increase federal outlays for Medicaid by $65 million over the 1998-2002 period.

Pay-as-you-go considerations: The Balanced Budget and Emergency Deficit Control Act of 1985 set up pay-as-you-go procedures for legislation affecting direct spending or receipts through 1998. CBO estimates that enactment of S. 830 would have no significant effect on direct spending or receipts in 1998.

VI. Regulatory Impact Statement

Estimated impact on State, local, and tribal governments: By preempting state and local laws that regulate nonprescription drugs differently than federal law, S. 830 would impose an intergovernmental mandate as defined in UMRA. CBO esti-

mates that compliance with this mandate would result in no significant costs for state and local governments. Consequently, the threshold established in UMRA ($50 million in 1996, adjusted annually for inflation) would not be exceeded. This mandate would not affect tribal governments.

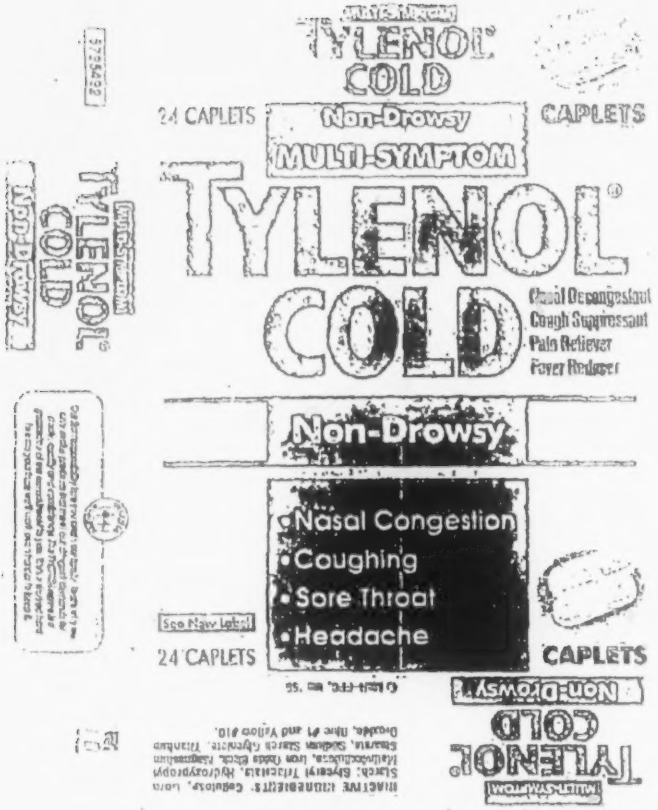
By granting certain drug manufacturers a six-month extension of market exclusivity for their products, the bill would make prescription drugs provided under Medicaid more expensive. CBO estimates that states' share of these costs would total about $28 million over the next five years. This provision would not constitute a mandate under UMRA because prescription drugs under Medicaid are provided at a state's option.

Estimated impact on the private sector: S. 830 would impose some new private-sector mandates and would replace some existing mandates with new, less burdensome requirements. In addition, the bill would reauthorize application fees and certain other fees paid by pharmaceutical companies. However, since these fees do not become effective until Congress appropriates them, they do not constitute a private-sector mandate. Thus, the direct cost of all private-sector mandates in this bill are minimal, and the total effect could be a net reduction in mandated costs imposed on the private sector.

Sections 803 and 808 would impose new mandates on the private sector. Section 803 would change the definition of when a food, drug, device, or cosmetic intended for export is not deemed to be adulterated or misbranded in situations in which exportation is made to the original foreign supplier. This section also would impose a new

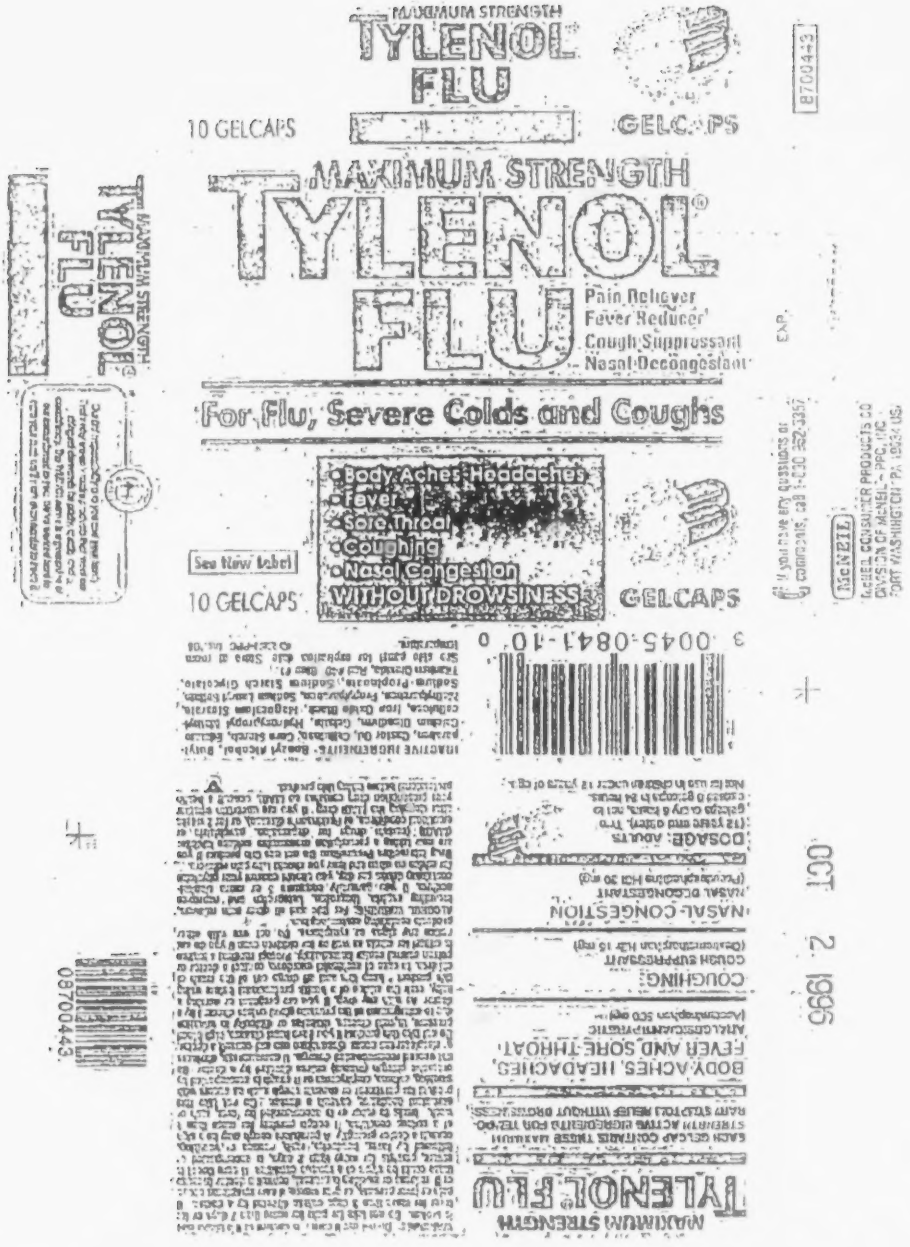
mandate on persons seeking to export a condemned imported article by imposing a new certification requirement. Section 808 would direct the Secretary to establish "a data bank of information on clinical trials for drugs, and biologicals, for serious or life-threatening diseases and conditions." This provision would impose a new mandate on sponsors of such clinical trials by requiring them to forward to the data bank information about eligibility criteria for participation in the trial, the location of the trial, and a point of contact within 21 days after the clinical trial is approved by FDA. CBO estimates that the costs of these mandates would be minimal.

Several new mandates would cost no more and perhaps less than the current regulatory requirements that they would replace. Section 601 would require manufacturers of medical devices to submit a written notice, rather than a supplemental application as currently required, for certain types of manufacturing changes. Section



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MAXIMUM STRENGTH
TYLENOL
FLU
10 GELCAPS
GELCAPS
MAXIMUM STRENGTH
TYLENOL®
FLU
Pain Reliever
Fever Reducer
Cough Suppressant
Nasal Decongestant
For Flu, Severe Colds and Coughs
Body Aches Headaches
Fever
Sore Throat
Coughing
Nasal Congestion
WITHOUT DROWSINESS
See New Label
10 GELCAPS
GELCAPS
8700443
McNEIL
McNEIL CONSUMER PRODUCTS CO
DIVISION OF McNEIL-PPC, INC
FORT WASHINGTON, PA 19034 USA
EXP.
0 0045-0841-10 0
TYLENOL FLU
MAXIMUM STRENGTH
DOSAGE: ADULTS
COUGHING
COUGH SUPPRESSANT
NASAL DECONGESTION
NASAL DECONGESTANT
BODY ACHES, HEADACHES,
FEVER AND SORE THROAT
ANALGESIC/ANTIPYRETIC
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[LETTERHEAD OF CONSUMER HEALTHCARE PRODUCTS ASSOCIATION]

OTC Facts and Figures

U.S. retail sales of over-the-counter (OTC) medicines in 2008 (excluding Wal-Mart) were $16.8 billion. (The Nielsen Company, 2009)

There are approximately 1,000 active ingredients used in the more than 100,000 OTC products available in the marketplace today. (CHPA, 2001)

Since 1976, 84 ingredients, dosages, or indications have made the "switch" from prescription to OTC status. Additionally, 15 medications were introduced during that time directly to the OTC market without having been prescription first. (CHPA, 2009)

More than 700 medicine products available over-the-counter today use ingredients and dosages that were available only by prescription less than 30 years ago. (CHPA, 2001)

Global OTC product sales totaled $72 billion worldwide in 2007. (IMS HEALTH, 2002)

77% of Americans take an OTC product to treat common, everyday ailments. (Roper Starch Worldwide, 2001)

Using OTC medications to treat common upper respiratory infections saves the U.S. healthcare system and economy $4.75 billion each year. (Northwestern University, 2004)

Consumer use of OTC heartburn medications saves the U.S. healthcare system $757 million annually, and saves the average consumer $174 annually. (CHPA and The Nielsen Company, 2009)

85% of American consumers think it is important to have access to OTCs to relieve minor medical problems. (American Pharmacists Association, 2000)

A majority of Americans (87%) believe that OTCs are safe when used as directed. (Roper Starch Worldwide, 2001)

82% of American women and 71% of American men have used a nonprescription medicine in the last six months to treat at least one common health ailment. (Roper Starch Worldwide, 2001)

Adults 65 years and older consume 33% of all OTC medicines sold in the United States. (American Pharmacists Association, 2000)

Of the more than $1.2 trillion spent on health care in 2000 in the United States, over $19 billion paid for nonprescription medicines - less than 2 cents of every health care dollar. (CHPA. 2001)

94 percent of consumers report satisfaction with available OTC heartburn remedies. (CHPA and The Nielsen Company, 2009)

65% of Americans wish that some of the prescription medicines they take would be made available over-the-counter, (National Consumers League, 2000)

Most individuals take the necessary precautions, such as reading directions before taking a nonprescription product for the first time (95%), reading labels to choose appropriate OTC medicines (89%), and reading about possible side effects and interactions (91%). (Roper Starch worldwide, 2001)

Over The Counter/Consumer Drug Manufacturers

Beiersdorf Inc.
P.O. Box 5529
Norwalk, CT 06856-5529
Mediphann Division: (203) 853-8008

Block Drug Company, Inc.
257 Comelison Avenue
Jersey City, NJ 07302
Medical Information: (201) 434-3000

Bristol-Myers Products
345 Park Avenue
New York, NY 10154
Medical Information: (800) 468-7746

Borroughs Welcome Co.
3030 Cornwallis Road
Research Triangle Park, NC 27709
Medical Information: (800) 443-6763

Chesebrough-Pond's Inc.
33 Benedict Place
Greenwich, CT 06830
Medical Information: (800) 243-5804

Ciba Self-Medication, Inc.
556 Morris Avenue
Summit, NJ 07901
Medical Information: (908) 602-6800

Del Pharmaceuticals, Inc.
163 East Bethpage Road
Plainview, NY 11803
Medical Information: (516) 293-7070

Johnson & Johnson Consumer Pharmaceuticals Co.
Grandview Road
Skillman, NJ 08558
Medical Information: (800) 526-3967

McNeil Consumer Products Company
Camp Hill Road
Fort Washington, PA 19034
Medical Information: (215) 233-7000

Mead Johnson Nutritionals
2400 West Lloyd Expressway
Evansville, IN 47721
Medical Information: (800) 429-5000

Merck Consumer Pharmaceuticals Co.
Camp Hill Road
Ft. Washington, PA 19034
Medical Information: (215) 233-7000
E-mail Merck

Miles Inc. Consumer Healthcare Products
1127 Myrtle Street
Elkhart, IN 46514
Medical Information: (800) 800-4793

Muro Pharmaceutical, Inc.
890 East Street
Tewksbury, MA 01876-1496
Medical Information: (800) 225-0974

Nature's Bounty, Inc.
90 Orville Drive
Bohemia, NY 11716
Medical Information: (800) 645-5412

Neutrogena Dermatologics
5760 West 96th Street
Los Angeles, CA 90045
Medical Information: (310) 642-1150

Ortho Pharmaceutical Corporation
Advanced Care Products
Route 202
P.O. Box 300
Raritan, NJ 08869-0602
Medical Information: (800) 682-6532

Pfizer Consumer Health Care
100 Jefferson Road
Parsippany, NJ 07054
Medical Information: (201) 887-2100

Proctor & Gamble Pharmaceuticals, Inc.
Sharon Woods Technical Center
11520 Reed Hartman Highway
Cincinnati, OH 45241
Medical Information: (800) 448-4878

Robins Consumer Products Division, A.H.
1405 Cummings Drive
Richmond, VA 23220
Medical Information: (610) 688-4400

Ross Products Division
Abbott Laboratories
Columbus, OH 43215-1724
Medical Information: (800) 227-5767

Sandoz Pharmaceuticals - Consumer Division
59 Route 10
East Hanover, NJ 07936
Medical Information: (201) 503-7500

SmithKline Beecham Consumer Healthcare, L.P.
P.O. Box 1467
Pittsburgh, PA 15230
Medical Information: (800) 233-2426

Sterling Health
A branch of Miles, Inc.
1127 Myrtle Street
Elkhart, IN 46514
Medical Information: (800) 800-4793

Thompson Medical Company, Inc.
222 Lakeview Avenue
West Palm Beach, FL 33401

Warner-Lambert Company
Consumer Health Products Group
201 Tabor Road
Morris Plains, NJ 07950
Medical Information: (800) 524-2854 or
(800) 223-0182

Whitehall Laboratories, Inc.
American Home Products Corporation
Five Giralda Farms
Madison, NJ 07940-0871
Medical Information: (800) 322-3129

[LETTERHEAD OF FDA U.S. FOOD AND DRUG ADMINISTRATION]

Drugs

Drug Applications for Over-the-Counter Drugs

Over-the-counter (Nonprescription) drugs play an increasingly vital role in America's health care system. Today, six out of every ten medications bought by consumers are OTC drugs. OTC drugs are defined as drugs that are safe and effective for use by the general public without seeking treatment by a health professional. FDA's review of OTC drugs is primarily handled by CDER's Office of Drug Evaluation IV, Over-the-Counter Drug Products. The Nonprescription Drug Advisory Committee meets regularly to assist the Agency in evaluating issues surrounding these products. This committee has played a major role in the growth of prescription to OTC switches in recent years.

Because there are over 300,000 marketed OTC drug products, FDA reviews the active ingredients and the labeling of over 80 therapeutic classes of drugs, for example analgesics or antacids, instead of individual drug products. For each category, an OTC drug monograph is developed and published in the *Federal Register*. OTC drug monographs are a kind of "recipe book" covering acceptable ingredients, doses, formulations, and labeling. Many of these monographs are found in section 300 of the *Code of Federal Regulations*[1]. Once a final monograph is implemented, companies can make and

market an OTC product without the need for FDA pre-approval. New prescription drugs, on the other hand, require pre-approval before they can go on the market. These monographs define the safety, effectiveness, and labeling of all marketing OTC active ingredients. New products that conform to a final monograph may be marketed without further FDA review. Those that do not conform must be reviewed by the **New Drug Application**[2] process. A drug company may also petition to change a final monograph to include additional ingredients or to modify labeling.

For more information about non-prescription drugs, visit the Office of Drug Evaluation IV home page[3]. This page also contains documents that are frequently requested of the Division.

Guidance Documents

Guidance documents represent the Agency's current thinking on a particular subject. These documents are prepared for FDA review staff and applicants/sponsors to provide guidelines to the processing, content, and evaluation/approval of applications and also to the design, production, manufacturing, and testing of regulated products. They also establish policies intended to achieve consistency in the Agency's regulatory approach and establish inspection and enforcement procedures. Because guidances are not regulations or laws, they are not enforceable, either through administrative actions or through the courts. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. For informa-

tion on a specific guidance document, please contact the originating office.

- **Over-the-Counter Drug Guidances**[4]
- Guidance for Industry: **National Uniformity for Nonprescription Drugs—Ingredient Listing for OTC Drugs**[5] (Issued 4/1998, Posted 5/5/1998). Describes how active and inactive ingredients must appear on OTC labels.

Laws, Regulations, Policies and Procedures

Federal Register

In the *Federal Register* of February 27, 1997 (62 FR 9024), FDA proposed a rule that would establish a standardized format for the labeling of OTC drug products. The rule is intended to make OTC drug product labeling easier to read and understand. The proposed rule includes a standardized format for listing the name and the quantity per dosage unit (or, when appropriate, the proportion) of each active ingredient. **Docket No. 98N-0337 Over the Counter Human Drugs Labeling Requirements**[6] is a collection of comments on the proposed rule submitted by the public, as well as FDA responses, meeting minutes, and other related materials.

- **Over-The-Counter Human Drugs; Labeling Requirements: Final rule**[7]. Effective Date: April 16, 1999. This final rule establishes a standardized format and standardized content requirements for the labeling of OTC drug products. The rule is

intended to assist consumers in reading and understanding OTC drug product labeling. All OTC drug products are required to carry the new, easy-to-read format and the revised content requirements within prescribed implementation periods.

Code of Federal Regulations

The final regulations published in the *Federal Register*[8] (daily published record of proposed rules, final rules, meeting notices, etc.) are collected in the *Code of Federal Regulations*[9]. The *CFR* is divided into 50 titles which represent broad areas subject to Federal regulations. The FDA's portion of the *CFR* interprets the *Federal Food, Drug and Cosmetic Act*[10] and related statutes. Section 21 of the *CFR*[11] contains all regulations pertaining to food and drugs. The regulations document all actions of all drug sponsors that are required under Federal law. Regulations of particular interest to OTC applicants include:

OTC Drug Products for existing Monographs

- **21 CFR Part 330—Over the-Counter (OTC) Human Drugs Which are Generally Recognized as Safe and Effective and not Misbranded**[12]. An OTC drug listed in subchapter 330 is generally recognized as safe and effective and is not misbranded if it meets the conditions of 330.1 and each of the conditions contained in the specific final monograph. As a basis for the scientific review of OTC ingredients, the CFR states definitions of safety, effectiveness, and labeling.

[STATE OF INDIANA, CRIMINAL JUSTICE INSTITUTE, PSEUDOEPHEDRINE PRODUCT LIST]

Disclaimer

This list contains Over the Counter (OTC) products that contain Pseudoephedrine and Ephedrine in all forms (gel-caps, liquids, nasal sprays, tablets, & caplets). This list is NOT comprehensive. This list was compiled as an aid in the identification of similar products in your store that contain Ephedrine or Pseudoephedrine. This list is a sample intended to reinforce or expand your general knowledge of products containing Ephedrine or Pseudoephedrine. The generic or store specific products that your store sells will likely not be included in this list. Each store will have its own unique brand(s) and will have its own name for the product. Many of the products will have similar names to those listed below. Simply because the product is not included, does not mean that it should not be treated as a product listed below. The key in the determination should be the ingredients (Ephedrine or Pseudoephedrine), not the name. Please also be aware that products continue to reformulated and renamed. We encourage all retailers to conduct a comprehensive search of their products and contact their wholesalers in order to identify products at your store that contain Ephedrine or Pseudoephedrine.

1. 4 COUGH & COLD
2. 4 COLD, FLU & COUGH
3. 12 HOUR ANTIHISTAMINE AND NASAL DECONGESTANT
4. 12 HOUR COLD CAPLETS

5. 12 HOUR COLD (DI)
6. 12 HOUR DECONGESTANT
7. 24-HOUR ALLERGY AND CONGESTION RELIEF
8. 24 HOUR ALLERGY RELIEF D
9. 666 COLD MAXIMUM STRENGTH
10. 666 COLD PREPARATION
11. ABLETEX PSE
12. ACCUHIST
13. ACCUHIST DM
14. ACCUHIST DM PEDIATRIC
15. ACCUHIST PDX
16. ACCUHIST PEDIATRIC
17. ACETAMINOPHEN & PSEUDO EPHEDRINE HYDROCHLORIDE
18. ACETAMINOPHEN, CHLORPHENIRAMINE, AND PSEUDOEPHEDRINE
19. ACETAMINOPHEN COLD
20. ACETAMINOPHEN FLU DAYTIME
21. ACETAMINOPHEN, PSEUDO EPHEDRINE HCL, DEXTROMETHORPHAN HBR AND CHLORPHENIRAMINE MALEATE
22. ACTACIN
23. ACTAGEN
24. ACTAGEN-C COUGH
25. ACTA-SYRUP
26. ACTIFED
27. ACTIFED 12 HOUR
28. ACTIFED ALLERGY
29. ACTIFED COLD & ALLERGY
30. ACTIFED COLD & SINUS
31. ACTIFED COLD AND SINUS
32. ACTIFED PLUS
33. ACTIFED PLUS (DI)

34. ACTIFED PLUS EXTRA STRENGTH
35. ACTIFED SINUS DAYTIME
36. ACTIFED SINUS DAYTIME/NIGHTTIME
37. ACTIFED SINUS NIGHTTIME
38. ACTIHIST
39. ADDED STRENGTH-D DECONGESTANT COUGH FORMULA
40. ADVIL ALLERGY SINUS
41. ADVIL FLU & BODY ACHE
42. AFRIN (DI)
43. AFRINOL
44. ALAVERT ALLERGY & SINUS D
45. ALEVE COLD AND SINUS
46. ALEVE SINUS AND HEADACHE
47. ALKA-SELTZER FLU LIQUI-GELS
48. ALKA-SELTZER PLUS COLD & COUGH CAPSULES
49. ALKA-SELTZER PLUS COLD & COUGH MEDICINE LIQUI-GELS
50. ALKA-SELTZER PLUS COLD & FLU MEDICINE LIQUI-GELS
51. ALKA-SELTZER PLUS COLD & SINUS CAPSULES
52. ALKA-SELTZER PLUS COLD MEDICINE
53. ALKA-SELTZER PLUS COLD MEDICINE LIQUI-GELS
54. ALKA-SELTZER PLUS FLU & BODY ACHES
55. ALKA-SELTZER PLUS NIGHT-TIME COLD
56. ALKA-SELTZER PLUS NIGHT-TIME COLD MEDICINE LIQUI-GELS
57. ALL-DAY AM MULTI-SYMPTOM COUGH AND COLD MEDICINE
58. ALLER-CHLOR

59. ALLERCON
60. ALLEREST ALLERGY & SINUS RELIEF
61. ALLEREST MAXIMUM STRENGTH
62. ALLEREST NO DROWSINESS
63. ALLEREST SINUS PAIN FORMULA
64. ALLERFED
65. ALLERFRIM
66. ALLERFRIN
67. ALLERGY
68. ALLERGY AND CONGESTION RELIEF
69. ALLERGY AND SINUS RELIEF
70. ALLERGY ANTIHISTAMINE AND NASAL DECONGESTANT
71. ALLERGY COLD
72. ALLERGY COLD (PM)
73. ALLERGY-D
74. ALLERGY/DECONGESTANT
75. ALLERGY DECONGESTANT COLD PAIN RELIEF
76. ALLERGY DECONGESTANT MEDICATION
77. ALLERGY RELIEF
78. ALLERGY RELIEF D
79. ALLERGY RELIEF D24
80. ALLERGY/SINUS HEADACHE MEDICINE
81. ALLERGY SINUS HEADACHE RELIEF
82. ALLERGY SINUS RELIEF
83. ALLERID (PM)
84. ALLERMED
85. ALLERPHED
86. ALLERPLUS
87. ALL-NITE
88. ALL-NITE COLD FORMULA
89. ALL-NITE COLD MEDICINE
90. ALL-NITE COLD MEDICINE LIQUID CAPS

91. ALL-NITE COLD RELIEF
92. AMBENYL-D
93. AMBENYL-D COUGH
94. AMERIFED
95. ANAFED
96. ANALGESIC DECONGESTANT ANTIHISTAMINIC REGULAR STRENGTH
97. ANAI.GESIC DECONGESTANT ANTIHISTAMINIC EXTRA STRENGTH
98. ANALGESIC DECONGESTANT ANTIHISTAMINIC REGULAR STRENGTH
99. ANALGESIC DECONGESTANT EXTRA STRENGTH
100. ANALGESIC DECONGESTANT REGULAR STRENGTH
101. ANALGESIC/NASAL DECONGESTANT COUGH SUPPRESSANT MAXIMUM STRENGTH
102. ANTI-ALLERGY
103. ANTIHISTAMINE
104. ANTIHISTAMINE 12 HOUR
105. ANTIHISTAMINE NASAL DECONGESTANT
106. APAP, DEXTROMETHORPHAN, DOXYLAMINE, AND PSEUDOEPHEDRINE
107. APHEDRID
108. APHE-DRY
109. APRODINE
110. APRODINE ANTIHISTAMINE AND NASAL DECONGESTANT
111. APRODINE SYRUP
112. ASPIRIN-FREE BAYER SELECT ALLERGY SINUS
113. ASPIRIN-FREE BAYER SELECT HEAD & CHEST COLD
114. ASTHMA TABS

115. ATHENOL COLD FORMULA
116. ATUSS-12 DM
117. BANOPHEN DECONGESTANT
118. BANOPHEN PLUS
119. BAYER SELECT
120. BAYER SELECT ALLERGY SINUS
121. BAYER SELECT FLU RELIEF
122. BAYER SELECT HEAD & CHEST COLD
123. BAYER SELECT HEAD COLD
124. BAYER SELECT MAXIMUM STRENGTH SINUS PAIN RELIEF
125. BAYER SELECT NIGHTTIME COLD
126. BC ALLERGY SINUS COLD
127. BC SINUS COLD MEDICATION FORMULA
128. BENADRYL ALLERGY AND SINUS
129. BENADRYL ALLERGY/COLD
130. BENADRYL ALLERGY COLD
131. BENADRYL ALLERGY CONGESTION
132. BENADRYL ALLERGY/DECONGESTANT
133. BENADRYL ALLERGY SINUS
134. BENADRYL ALLERGY SINUS HEADACHE
135. BENADRYL COLD
136. BENADRYL COLD & FLU
137. BENADRYL COLD & FLU (PM)
138. BENADRYL COLD NIGHTTIME FORMULA
139. BENADRYL DECONGESTANT
140. BOCA-TEX PSE
141. BREXIN EX
142. BREXIN (PM) (DI)
143. BREXIN LA
144. BROMALINE
145. BROMALINE DM

146. BROMANATE
147. BROMANATE DM COUGH AND COLD
148. BROMAREST DX
149. BROMAXAFED RF
150. BROMAXEFED DM RF
151. BROMFED
152. BROMPHENIRAMINE AND PSEUDO EPHEDRINE
153. BROMPHERIL
154. BROMTAPP
155. BROMTAPP COLD &ALLERGY
156. BROMTAPP DM
157. BROMTAPP ELIXIR DM
158. BRONKAID
159. BRONKAID DUAL ACTION FORMULA
160. BRONKOLIXIR
161. BROTAPP
162. BROTAPP-DM
163. CENAFED PLUS
164. CEPACOL SORE THROAT LIQUID
165. CETAFEN COLD
166. CHEST AND NASAL CONGESTION
167. CHILDRENS ADVIL COLD
168. CHILDREN'S ALLERGY
169. CHILDREN'S ALL-NITE
170. CHILDREN'S ALL NITE COLD MEDICINE
171. CHILDREN'S BENADRYL ALLERGY AND SINUS
172. CHILDREN'S BENADRYL ALLERGY COLD FASTMELT
173. CHILDRENS CEPACOL
174. CHILDREN'S CEPACOL SORE THROAT LIQUID – CHERRY

175. CHILDREN'S CEPACOL SORE THROAT LIQUID – GRAPE
176. CHILDREN'S COLD
177. CHILDREN'S COLD & COUGH
178. CHILDREN'S COLD & PAIN
179. CHILDREN'S COLD AND ALLERGY
180. CHILDREN'S COLD PLUS COUGH
181. CHILDREN'S CONGESTION
182. CHILDREN'S COUGH AND SORE THROAT
183. CHILDREN'S DAYQUIL ALLERGY
184. CHILDREN'S DIMETAPP NIGHTIME FLU
185. CHILDREN'S DIMETAPP NON-DROWSY FLU
186. CHILDREN'S ELIXIR
187. CHILDREN'S ELIXSURE
188. CHILDREN'S FLU
189. CHILDREN'S IBUPROFEN COLD
190. CHILDREN'S MAPAP COLD
191. CHILDREN'S MOTRIN COLD
192. CHILDREN'S MULTI-SYMPTOM COLD
193. CHILDREN'S NASAL DECONGESTANT
194. CHILDREN'S NI-CALM
195. CHILDREN'S NIGHTTIME
196. CHILDREN'S NIGHT TIME COLD FORMULA
197. CHILDREN'S NITE TIME
198. CHILDREN'S NITE TIME COLD
199. CHILDREN'S NITE-TIME COLD FORMULA
200. CHILDREN'S NITE-TIME COUGH SUPPRESSANT, ANTIHISTAMINE AND NASAL DECONGESTANT

201. CHILDREN'S NITE-TIME COUGH SUPPRESSANT, ANTIHISTAMINE AND NASAL DECONGESTANT
202. CHILDREN'S NO-ASPIRIN FLU FORMULA
203. CHILDREN'S NON-ASPIRIN COLD
204. CHILDREN'S NON-ASPIRIN COLD AND COUGH
205. CHILDREN'S NON-ASPIRIN COLD PLUS COUGH
206. CHILDREN'S NON-ASPIRIN FLU
207. CHILDREN'S NYQUIL NIGHTTIME COLD/COUGH
208. CHILDREN'S PAIN & COLD RELIEF
209. CHILDREN'S PAIN RELIEF
210. CHILDREN'S PAIN RELIEVER
211. CHILDREN'S PAIN RELIEVER COLD
212. CHILDREN'S PAIN RELIEVER FLU
213. CHILDREN'S PAIN RELIEVER MULTI SYMPTOM COLD PLUS COUGH
214. CHILDREN'S PHED
215. CHILDREN'S PSEUPHEDRIN
216. CHILDREN'S SUDAFED
217. CHILDREN'S SUDAFED COLD & COUGH
218. CHILDREN'S SUDAFED NASAL DECONGESTANT
219. CHILDREN'S SUDAFED NASAL DECONGESTANT CHEWABLES
220. CHILDREN'S SUPHEDRIN
221. CHILDREN'S SUPHEDRINE
222. CHILDREN'S TRIACTIN COLD AND ALLERGY
223. CHILDREN'S TYLENOL ALLERGY-D
224. CHILDREN'S TYLENOL COLD

225. CHILDREN'S TYLENOL COLD MULTI-SYMPTOM PLUS COUGH
226. CHILDREN'S TYLENOL FLU
227. CHILDREN'S TYLENOL SINUS
228. CHILDREN'S WAL-PHED
229. CHILDREN'S WAL-TAP
230. CHLOR-TRIMETON ALLERGY DECONGESTANT 4 HOUR
231. CHLOR-TRIMETON ALLERGY DECONGESTANT 12 HOUR
232. CHLOR-TRIMETON LONG-ACTING DECONGESTANT
233. CHLOR-TRIMETON NON-DROWSY DECONGESTANT 4 HOUR
234. CO-ADVIL
235. CODIMAL
236. COLD & ALLERGY
237. COLD & ALLERGY RELIEF 12 HOUR
238. COLD & COUGH MEDICINE PLUS
239. COLD & COUGH SUPER TUSSIN
240. COLD & NIGHT TIME COUGH
241. COLD AND ALLERGY
242. COLD AND ALLERGY DECONGESTANT
243. COLD AND ALLERGY RELIEF
244. COLD AND COUGH
245. COLD AND COUGH ELIXIR DM
246. COLD CAPLETS
247. COLD CAPS
248. COLD CONTROL PLUS
249. COLD DECONGESTANT NON-DROWSY, MAXIMUM STRENGTH
250. COLD FORMULA
251. COLD FORMULA FOR NIGHT-TIME RELIEF
252. COLD FORMULA LIQUID CAPSULES

253. COLD MEDICINE PLUS
254. COLDMIST DM
255. COLD MULTI-SYMPTOM MAXIMUM STRENGTH
256. COLD MULTI-SYMPTOM RELIEF
257. COLD RELIEF
258. COLD RELIEF CHILDREN'S
259. COLD RELIEF PLUS
260. COLD TABLETS
261. COMPLETE
262. COMPLETE COLD
263. COMPLETE COLD RELIEF
264. COMTREX
265. COMTREX ACUTE HEAD COLD
266. COMTREX DAY AND NIGHT
267. COMTREX DEEP CHEST COLD
268. COMTREX FLU THERAPY
269. COMTREX NON-DROWSY
270. CONCENTRIN
271. CONTAC
272. CONTAC DAY & NIGHT ALLERGY SINUS
273. CONTAC JR.
274. CONTAC SEVERE COLD & FLU
275. CONTAC SEVERE COLD & FLU HOT MEDICINE
276. CONTAC SEVERE COLD & FLU NIGHTTIME
277. CONTAC SEVERE COLD AND FLU
278. CONTAC SINUS
279. COUGH & COLD FORMULA CHILDREN'S
280. COUGH & HEAD CONGESTION RELIEF D
281. COUGH & NASAL DECONGESTANT
282. COUGH AND COLD

283. COUGH AND COLD FORMULA PEDIATRIC
284. COUGH FORMULA
285. COUGH FORMULA CF
286. COUGH FORMULA-D, DECONGESTANT
287. COUGH FORMULA DPG
288. COUGH FORMULA M
289. COUGH MIXTURE, EXTRA STRENGTH DECONGESTANT
290. COUGH SORE THROAT CONGESTION FORMULA
291. COUGH SYRUP CF
292. COUGH SYRUP D
293. COUGH SYRUP PE
294. CREMACOAT
295. CREOMULSION COMPLETE
296. CREOMULSION PEDIATRIC COUGH, COLD, ALLERGY FORMULA
297. DALLERGY-D
298. DAY CALM
299. DAYQUIL
300. DAYQUIL
301. DAYQUIL NON-DROWSY COLD/FLU MEDICINE
302. DAYQUIL SINUS PRESSURE AND PAIN RELIEF WITH IBUPROFEN
303. DAY TIME
304. DAYTIME COLD
305. DAY TIME COLD FORMULA
306. DAY TIME COLD MEDICINE LIQUID CAPS
307. DAY TIME LIQUID CAPS
308. DAY TIME MULTI-SYMPTOM
309. DAY-TIME MULTI-SYMPTOM COLD AND FLU

310. DAY TIME NON-DROWSY
311. DECONGESTABS
312. DECONGESTANT
313. DECONGESTANT COUGH FORMULA D
314. DECONGESTANT INHALER
315. DEXAPHEN
316. DIBROMM
317. DIBROMM COLD AND ALLERGY CHILDREN'S
318. DIBROMM DM
319. DIBROMM EXTENDED-RELEASE NASAL DECONGESTANT
320. DIMAPHEN
321. DIMAPHEN DM
322. DIMETAPP 12-HOUR EXTENTABS
323. DIMETAPP COLD AND ALLERGY
324. DIMETAPP DAYTIME NON-DROWSY FLU
325. DIMETAPP DM COLD AND COUGH
326. DIPHEDRYL
327. DIPHEDRYL ALLERGY/SINUS HEADACHE
328. DISOPHROL
329. DISOPHROL CHRONOTAB
330. DIXADRINE
331. DIXAPHED
332. DIXAPHEDRINE
333. DORCOL CHILDREN'S COLD FORMULA
334. DORCOL CHILDREN'S COUGH
335. DORCOL CHILDREN'S DECONGESTANT
336. DORCOL PEDIATRIC FORMULA CHILDREN'S COUGH SYRUP
337. DORCOL PEDIATRIC FORMULA CHILDREN'S COUGH SYRUP

338. DRISTAN COLD NO DROWSINESS FORMULA
339. DRIXORAL
340. DRIXORAL ALLERGY SINUS
341. DRIXORAL COLD & ALLERGY
342. DRIXORAL COUGH & CONGESTION
343. DUADACIN COLD/FLU EXTRA STRENGTH
344. DURATION 12-HOUR
345. E-D
346. EFED 11
347. ELIXSURE CONGESTION
348. EPHEDRINE AND GUAIFENESIN
349. EPHEDRINE HYDROCHLORIDE
350. EPHEDRINE, PHENOBARBITAL, AND THEOPHYLLINE
351. EPHEDRINE PLUS
352. EPHEDRINE SULPHATE
353. EPHEDRIX
354. EXCEDRIN EXTRA STRENGTH SINUS
355. EXTRA STRENGTH TYLENOL FLU
356. FEDAHIST
357. FEDRIN
358. FLU & COLD MEDICINE
359. FLU, COLD & COUGH MAXIMUM STRENGTH
360. FLU, COLD, AND COUGH MEDICINE
361. FLU, COLD, AND COUGH RELIEF
362. FLU, COUGH & COLD
363. FLU FORMULA
364. FLU MEDICINE
365. FLU MULTI-SYMPTOM MAXIMUM STRENGTH
366. FLU, SEVERE COLD AND CONGESTION

367. FORMULA 44 COUGH & COLD, PEDIATRIC
368. FORMULA 465 NIGHTTIME MEDICINE FOR COLDS
369. FORMULA COLD & COUGH
370. FORMULA D
371. FORMULA DM
372. GENAC
373. GFN 550/PSE 60
374. GFN 595/PSE 48
375. GFN 595/PSE 48/DM 32
376. GFN 795/PSE 85
377. GFN 800 AND PSE 60
378. GFN 800/PSE 60/DM 30
379. GUAIFENESIN 600/PSE 120
380. GUIATUSS CF
381. HALOFED
382. HALOTUSSIN
383. HAYFEVER RELIEF PLUS
384. HISTAFED
385. HISTA-TABS
386. HONEY TUSSIN COLD
387. HUMIBID PLUS
388. IBUPROFEN COLD AND SINUS
389. INFANT DECONGESTANT
390. INFANTS' COLD DROPS
391. INFANTS NON-ASPIRIN COLD DROPS
392. INFANTS' NON-ASPIRIN COLD PLUS COUGH
393. INFANTS' PAIN RELIEVER COLD
394. INFANTS PEDIA RELIEF DECONGESTANT PLUS COUGH
395. INFANTS PEDIA RELIEF NASAL DECONGESTANT
396. INFANTS TYLENOL COLD PLUS COUGH

397. ISOCLOR
398. KENAHIST PLUS
399. KIDKARE COUGH & COLD
400. KIDKARE DECONGESTANT
401. KNOL MAXIMUM STRENGTH ALLERGY SMUS MEDICATION
402. KOL-SPANS
403. LANTUSS-DM
404. LIQUID CAPSULES
405. LIQUITUSSIN COLD & COUGH
406. LORATA-D
407. LORATA-DINE D
408. MAPAP SINUS MAXIMUM STRENGTH
409. MARDROPS
410. MAX ALERT MINI-TABS
411. MAXIMUM STRENGTH ALLERGY SINUS
412. MAXIMUM STRENGTH COLD
413. MAXIMUM STRENGTH COUGH, COLD AND FLU
414. MAXIMUM STRENGTH EFEDRIN BRONCHODILATOR
415. MAXIMUM STRENGTH MEDI-TABS ALLERGY/SMUS
416. MAXIMUM STRENGTH MULTI-SYSPTOM COLD RELIEVER
417. MAXIMUM STRENGTH NASAL DECONGESTANT
418. MAXIMUM STRENGTH NON-ASPIRIN SINUS
419. MAXIMUM STRENGTH SINUS
420. MAXIMUM STRENGTH SINUS FORMULA
421. MAXIMUM STRENGTH SINUTAB NON-DROWSY
422. MAXIMUM STRENGTH SUDAFED SEVERE COLD FORMULA

423. MAXIMUM STRENGTH TYLENOL SINUS
424. MEDI-BROM
425. MEDI-FLU
426. MEDI-FLU WITHOUT DROWSINESS
427. MEDI-PHEDRINE 12 HOUR
428. MEDI-PHEDRME MAXIMUM STRENGTH
429. MEDI-PHEDRINE SEVERE COLD FORMULA
430. MEDI-PHEDRYL
431. MEDIQUELL
432. MEDI-TABS FLU
433. MEDI-TUSSIN COUGH & COLD
434. MINIC
435. MINIC COLD AND ALLERGY
436. MINIC EXPECTORANT
437. MINTAB C
438. MINI THIN 2 WAY ACTION
439. MOTRIN COLD & FLU
440. MOTRIN COLD AND SINUS
441. MOTRIN COLD CHILDREN'S
442. MOTRIN SINUS HEADACHE
443. MULTI COLD
444. MULTIPLE SYMPTOM COLD
445. MULTIPLE SYMPTOM COLD RELIEF
446. MULTIPLE-SYMPTOM COLD RELIEVER
447. MULTIPLE SYMPTOM COUGH/COLD
448. MULTI-SYMPTOM ALLERGY SINUS
449. MULTI-SYMPTOM COLD
450. MULTI-SYMPTOM MEDI-TABS COLD
451. MULTI-SYMPTOM NON-ASPIRIN COLD
452. MULTI-SYMPTOM PSEUDOEPHEDRINE COLD AND COUGH
453. MULTI-SYMPTOM RELIEF ALLERGY SINUS
454. MULTI-SYMPTOM SUPHEDRIN

455. MULTI-SYMPTOM SUPHEDRINE SEVERE COLD
456. MULTI-SYMPTOM TYLENOL COUGH WITH DECONGESTANT
457. MYFEDRINE
458. NAPRIL
459. NASAL & SINUS DECONGESTANT 12 HOUR
460. NASAL AND SINUS DECONGESTANT
461. NASAL DECONGESTANT
462. NASAL DECONGESTANT ANTIHISTAMINE
463. NASAL DECONGESTANT D COUGH
464. NASAL RELIEF MAXIMUM STRENGTH
465. NI-CALM
466. NI-CALM LIQUID CAPS
467. NIGHT TIME
468. NIGHTTIME
469. NIGHT TIME COLD
470. NIGHTTIME COLD MEDICINE
471. NIGHT TIME COLD MEDICINE LIQUID CAPS
472. NIGHT TIME MULTI-SYMPTOM COLD AND FLU RELIEF
473. NITE-A-REST
474. NITE CARE
475. NITE CARE COLD FORMULA
476. NITE CARE LIQUID CAPS
477. NITE TIME
478. NITE-TIME
479. NITE-TIME CHILDREN'S
480. NITE TIME COLD
481. NITE TIME COLD FORMULA
482. NITE TIME COUGH FORMULA
483. NITE TIME LIQUID CAPS

484. NON-ASPIRIN ALLERGY AND SINUS
485. NON-ASPIRIN ALLERGY SINUS MAXIMUM STRENGTH
486. NON-ASPIRIN COLD
487. NON-ASPIRIN COLD MEDICINE
488. NON-ASPIRIN COLD MULTI-SYMPTOM
489. NON-ASPIRIN FLU
490. NON-ASPIRIN FLU MAXIUMUM STRENGTH
491. NON ASPIRIN FLU NIGHTTIME FORMULA
492. NON-ASPIRIN SINUS
493. NON-ASPIRIN SINUS ALLERGY
494. NON-ASPIRIN SINUS MAXIMUM STRENGTH
495. NON DROWSY COLD CAPS
496. NON-DROWSY FLU
497. NON-DROWSY MULTI-SYMPTOM COLD
498. NON-DROWSY NASAL DECONGESTANT
499. NON-DROWSY SINUS
500. NON-DRYING SINUS MAXIMUM STRENGTH
501. NOVAGEST DEX
502. NYQUIL MULTISYMPTOM COLD AND FLU RELIEF
503. OHMNI-CO-ALL
504. OHMNI-MED
505. ORIGINAL FORMULA FLU
506. ORNEX
507. PAIN RELIEF ALLERGY SINUS
508. PAIN RELIEF ALLERGY SINUS MAXIMUM STRENGTH
509. PAIN RELIEF COLD
510. PAIN RELIEF COLD MULTI-SYMPTOM
511. PAIN RELIEF FLU

512. PAIN RELIEF SINUS
513. PAIN RELIEVER ALLERGY SINUS
514. PAIN RELIEVER ALLERGY SINUS MEDICATION, MAXIMUM STRENGTH
515. PAIN RELIEVER COLD
516. PAIN RELIEVER COLD AND COUGH
517. PAIN RELIEVER COLD MEDICATION
518. PAIN RELIEVER SINUS
519. PAIN RELIEVER SINUS MAXIMUM STRENGTH
520. PATHADINE NASAL DECONGESTANT ANTIHISTAMINE
521. PATHADRYL
522. PATHAMINE
523. PATHATUSSIN COLD & COUGH
524. PAZO
525. PEDIACARE COLD AND ALLERGY CHILDREN'S
526. PEDIACARE COLD-COUGH
527. PEDIACARE COUGH AND COLD CHILDREN'S
528. PEDIACARE COUGH-COLD
529. PEDIACARE DECONGESTANT INFANTS
530. PEDIACARE DECONGESTANT PLUS COUGH
531. PEDIACARE MULTI-SYMPTOM COLD CHILDREN'S
532. PEDIACARE NIGHTREST
533. PEDIA RELIEF COUGH AND COLD
534. PEDIA RELIEF INFANTS'
535. PEDIATRIC PLUS
536. PEDIATRIC NASAL DECONGESTANT PLUS COUGH
537. PEDIATUSS NR
538. PHED PLUS

539. PHENAPP CHLOR
540. POLY-VENT JR
541. PROFEN IB
542. PROPRINAL
543. PSEUDO-CAPS 12 HOUR
544. PSEUDO-CAPS SINUS MAXIMUM STRENGTH
545. PSEUDO-TABS
546. PSEUDOTABS SEVERE COLD FORMULA MAXIMUM STRENGTH
547. PSEUDOVAL PLUS
548. PSEUDOVAL SEVERE
549. PSUDA CAPS
550. PSUDA-TABS
551. PSUDA-TABS PLUS
552. PSUDA-TABS SEVERE COLD FORMULA
553. PYRROXATE EXTRA STRENGTH
554. Q-FED
555. Q-TAPP DM
556. Q-TUSSIN CF
557. Q-TUSSIN PE
558. QUAD TANN PEDIATRIC
559. QUIET NITE COLD MEDICINE
560. QUIET NITE COUGH SYRUP
561. REST EASY, CHILDREN'S
562. REVIVE COLD
563. ROBAFEN CF
564. ROBAFEN COLD AND COUGH
565. ROBAFEN PEDIATRIC COUGH AND COLD
566. ROBAFEN SEVERE CONGESTION
567. ROBITUSSIN ALLERGY AND COUGH
568. ROBITUSSIN CF
569. ROBITUSSIN COLD

570. ROBITUSSIN COLD & COUGH LIQUIGELS
571. ROBITUSSIN COLD NIGHT-TIME LIQUIGELS
572. ROBITUSSIN COLD SEVERE CONGESTION LIQUIGELS
573. ROBITUSSIN COUGH & COLD INFANT DROPS
574. ROBITUSSIN HONEY FLU MULTI-SYMPTOM
575. ROBITUSSIN HONEY FLU NIGHTTIME
576. ROBITUSSIN-PE
577. ROBITUSSIN SEVERE CONGESTION
578. ROLATUSS EXPECTORANT
579. SEVERE COLD &FLU
580. SEVERE COLD AND FLU MAXIMUM STRENGTH
581. SEVERE COLD FORMULA
582. SEVERE COLD SUPHEDRINE
583. SEVERE CONGESTION
584. SINAREST EXTRA STRENGTH
585. SINAREST SINUS
586. SINE-AID IB, IBUPROFEN STRENGTH
587. SINE-OFF
588. SINE-OFF ALLERGY/SINUS MAXIMUM STRENGTH
589. SINE-OFF MAXIMUM STRENGTH
590. SINE-OFF NO DROWSINESS
591. SINGLET
592. SINUCLEAR
593. SINU-PREP
594. SINUS
595. SINUS & ALLERGY
596. SINUS 12 HOUR
597. SINUS ALLERGY MAXIMUM STRENGTH

598. SINUS AND NASAL RELIEF
599. SINUS CAPLETS
600. SINUS EXCEDRIN
601. SINUS EXTRA STRENGTH
602. SINUS GELATIN CAPLETS
603. SINUS LIQUID CAPS
604. SINUS MAXIMUM STRENGTH
605. SINUS MAXIMUM STRENGTH WITHOUT DROWSINESS
606. SINUS, NON-DROWSINESS FORMULA
607. SINUSON
608. SINUS RELIEF
609. SINUS RELIEF, MAXIMUM STRENGTH
610. SINUS TABLET II
611. SINUS TABS
612. SINUSTABS
613. SINUS WITHOUT DROWSINESS
614. SINUTAB
615. SINUTAB MAXIMUM STRENGTH
616. SINUTAB NON-DRYING
617. SINUTAB SINUS
618. SINUTAB SINUS ALLERGY
619. SINUTAB SINUS WITHOUT DROWSINESS
620. ST. JOSEPH NIGHTTIME COLD MEDICINE
621. SUCRETS PAIN RELIEF COUGH FORMULA
622. SUDACHEM
623. SUDAFED
624. SUDAFED 12 HOUR
625. SUDAFED 24 HOUR
626. SUDAFED CHILDREN'S FORMULA
627. SUDAFED CHILDREN'S NON-DROWSY FORMULA

628. SUDAFED COLD & ALLERGY
629. SUDAFED COLD & COUGH
630. SUDAFED COLD & COUGH CHILDREN'S
631. SUDAFED COLD AND SINUS
632. SUDAFED NASAL DECONGESTANT
633. SUDAFED NASAL DECONGESTANT CHILDREN'S
634. SUDAFED NASAL DECONGESTANT PEDIATRIC
635. SUDAFED NON-DRYING SINUS
636. SUDAFED PLUS
637. SUDAFED SEVERE COLD FORMULA
638. SUDAFED SINUS AND ALLERGY
639. SUDAFED SINUS AND COLD
640. SUDAFED SINUS HEADACHE
641. SUDAFED SINUS NIGHTIME
642. SUDO GEST
643. SUDOGEST CHILDREN'S
644. SUDOGEST SINUS MAXIMUM STRENGTH
645. SUPER TUSSIN
646. SUPER TUSSIN CF
647. SUPER TUSSIN PEDIATRIC COUGH & COLD
648. SUPHEDRIN
649. SUPHEDRIN 12 HOUR
650. SUPHEDRIN COLD AND ALLERGY
651. SU-PHEDRINE CHILDREN'S
652. SUPHEDRINE COLD & COUGH
653. SUPHEDRINE MAXIMUM STRENGTH
654. SUPHEDRINE NASAL DECONGESTANT
655. SUPHEDRINE PLUS
656. SUPHEDRINE PLUS MAXIMUM STRENGTH
657. SUPHEDRINE SEVERE COLD FORMULA

658. SUPHEDRINE SINUS
659. SU-PHEDRIN SEVERE COLD FORMULA
660. TAVIST SINUS
661. THEOLIXER
662. THEOPHENYLLIN
663. THEOTAL
664. THERACAPS INTENSE STRENGTH
665. THERAFLU
666. THERAFLU COLD MEDICINE, NIGHT-TIME STRENGTH
667. THERAFLU FLU, COLD, AND COUGH
668. THERA-FLU MAXIMUM STRENGTH
669. THERAFLU MAXIMUM STRENGTH FLU AND COLD
670. THERAFLU MAXIMUM STRENGTH FLU, COLD & COUGH
671. THERAFLU MAXIMUM STRENGTH NIGHTTIME FLU, COLD & COUGH
672. THERAFLU SINUS
673. THERA-HIST
674. THERA-HIST CHEST CONGESTION
675. THERA-HIST COLD AND ALLERGY
676. THERA-HIST COLD AND COUGH
677. THERA-HIST EXPECTORANT
678. THERMAPRO
679. TRIAC
680. TRI-ACT
681. TRIACTIN
682. TRI ACTING
683. TRIACTING CHEST CONGESTION
684. TRIACTING COLD AND ALLERGY
685. TRIACTING COLD AND COUGH
686. TRIACTING EXPECTORANT
687. TRIACTING NITE TIME MAXIMUM STRENGTH

688. TRIACTING SORE THROAT FORMULA
689. TRIACTIN SORE THROAT, COUGH AND COLD
690. TRIAMINIC ALLERGY CONGESTION
691. TRIAMMIC AM COUGH & DECONGESTANT
692. TRIAMMIC AM DECONGESTANT
693. TRIAMINIC COLD & FEVER
694. TRIAMINIC COLD AND ALLERGY
695. TRIAMINIC COLD AND COUGH
696. TRIAMINIC COLD AND NIGHT TIME COUGH
697. TRIAMINIC COUGH
698. TRIAMINIC COUGH AND CONGESTION
699. TRIAMINIC COUGH AND SORE THROAT
700. TRIAMINIC DM NIGHTTIME
701. TRIAMINIC FLU, COUGH AND FEVER
702. TRIAMINIC INFANT
703. TRIAMINIC NIGHT TIME MAXIMUM STRENGTH
704. TRIAMINIC SEVERE COLD & FEVER
705. TRIAMINIC SORE THROAT
706. TRIANAMINE
707. TRIANAMINE COLD AND ALLERGY
708. TRIFEDRINE
709. TRIFEDRINE NASAL DECONGESTANT AND ANTIHISTAMINE
710. TRIPROLIDINE & PSEUDOEPHEDRINE
711. TRU-QUIL CHILDREN'S
712. TUSSIN CF
713. TUSSIN COLD
714. TUSSIN COLD & COUGH
715. TUSSIN COUGH AND COLD MAXIMUM STRENGTH

716. TUSSIN MAXIMUM STRENGTH COUGH & COLD MEDICINE
717. TUSSIN PE
718. TUSSIN PE COUGH FORMULA
719. TUSSIN PEDIATRIC COUGH & COLD
720. TUSSIN SEVERE CONGESTION
721. TY-COLD
722. TYLENOL ALLERGY SINUS
723. TYLENOL ALLERGY SINUS NIGHT TIME
724. TYLENOL ALLERGY SINUS NIGHTTIME MAXIMUM STRENGTH
725. TYLENOL COLD
726. TYLENOL COLD & FLU
727. TYLENOL COLD & FLU HOT MEDICATION HONEY LEMON FLAVOR
728. TYLENOL COLD COMPLETE FORMULA
729. TYLENOL COLD DAY/NIGHT
730. TYLENOL COLD MULTI-SYMPTOM
731. TYLENOL COLD MULTI-SYMPTOM HOT MEDICATION
732. TYLENOL COLD SEVERE CONGESTION
733. TYLENOL COUGH WITH DECONGESTANT
734. TYLENOL COUGH WITH DECONGESTANT MEDICATION MAXIMUM STRENGTH
735. TYLENOL FLIJ MAXIMUM STRENGTH
736. TYLENOL FLU NIGHTTIME MAXIMUM STRENGTH
737. TYLENOL FLU NIGHTTIME MAXIMUM STRENGTH
738. TYLENOL SINUS NIGHTTIME MAXIMUM STRENGTH
739. TYLTABS ALLERGY SINUS
740. UNI-HIST DM

741. URSINUS INLAY
742. VA-TRO-NOL
743. VALU-DRYL
744. VALU-DRYL ALLERGY AND SINUS HEADACHE
745. VALU-TAPP
746. VICKS 44 COLD, FLU & COUGH
747. VICKS 44D COUGH AND HEAD CONGESTION
748. VICKS 44 LIQUICAPS COLD, FLU & COUGH
749. VICKS 44 LIQUICAPS NON-DROWSY COLD & COUGH
750. VICKS 44M COUGH, COLD, AND FLU
751. VICKS 44M PEDIATRIC
752. VICKS DAYQUIL LIQUICAPS MULTI-SYMPTOM COLD/FLU RELIEF
753. VICKS DAYQUIL MULTI-SYMPTOM
754. VICKS DAYQUIL MULTI-SYMPTOM COLD/FLU RELIEF
755. VICKS DAYQUIL SINUS PRESSURE & PAIN RELIEF
756. VICKS FORMULA 44D COUGH & DECONGESTANT
757. VICKS NYQUIL ADULT NIGHTTIME COLD/FLU MEDICATION
758. VICKS NYQUIL CHILDREN'S
759. VICKS NYQUIL HOT THERAPY ADULT NIGHTTIME HOT LIQUID COLD/FLU MEDICINE
760. VICKS NYQUIL LIQUICAPS MULTI-SYMPTOM COLD/FLU RELIEF
761. VICKS VAPOR INHALER
762. WAL-ACT
763. WAL-ITIN D

764. WAL-MINIC COLD AND ALLERGIES
765. WAL-MINIC COLD AND NIGHT TIME COUGH
766. WAL-PHED
767. WAL-PHED 12 HOUR
768. WAL-PHED DECONGESTANT
769. WAL-PHED NASAL DECONGESTANT
770. WAL-PHED NON-DRYING SINUS
771. WAL-PHED SEVERE COLD FORMULA
772. WAL-PHED SINUS
773. WAL-PROFEN COLD AND SINUS
774. WAL-TAPP DM
775. WAL-TUSSIN
776. WAL-TUSSIN CF
777. WAL-TUSSIN PE